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TOPICAL REVIEW

A Review on Statistical Process Control in Healthcare: Data-Driven Monitoring Schemes

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ABSTRACT In recent years, the adoption of statistical process monitoring (SPM) techniques in healthcare has been successful. For instance, biosurveillance and biosignal monitoring have demonstrated direct benefits. As the latest reviews of the literature show, parametric SPM techniques have been implemented to evaluate the quality-of-service hospitals provide, track medical equipment, monitor safety markers, or assess the improvements made by quality projects. However, as shown in this research, world-trending topics in data science that include data-driven approaches integrated with SPM have not been reviewed. To bridge this gap and shed light on new research, a systematic review of scientific databases and a taxonomic literature analysis were performed. For the scientometric analysis, a set of bibliometric indicators were obtained to portray the performance of each subtopic, such as examining growth kinetics, identifying top authors, journals, countries and affiliations, as well as creating network maps of co-authorship and keyword co-occurrence. Additionally, the taxonomic analysis involved grouping proposals by methodological approach. Each approach was explained and discussed to identify the advantages, limitations, and challenges that researchers and practitioners may encounter. SPM researchers and practitioners require more flexibility in data-driven approaches to account for frequency unbalance, complexity, dimensionality problems, and speed. Those working in data-driven and computer-oriented areas can expand their toolbox by incorporating sequential approaches to enhance the power of their classifiers, assess risk, reduce misspecification, and adopt model-oriented mindsets.

INDEX TERMS Data-driven, healthcare, scientometric, statistical process monitoring.

I. INTRODUCTION

Statistical *process monitoring* (SPM), also known as *statistical process control* (SPC), encompasses a set of tools designed to assess process stability and enhance capability by reducing variability [1]. The core tools of SPM are *control charts*, which include a set of sequential approaches for monitoring the occurrence of process shifts, either isolated or sustained, in location, scale, or form, to assist the search and learning through the detection of assignable causes of variation. Control charts typically consist of a monitoring statistic that is evaluated against one or more control limits. These control limits indicate whether the process is assumed to be *in control* (IC) or potentially *out of control* (OC). If the charting statistic falls outside the control limits or triggers an OC signal, the search for assignable causes begins to regain control [2].

Traditional control charts for both univariate and multivariate processes can be primarily grouped into four classes [3]: *Shewhart* charts, *cumulative sum* (CUSUM) charts, *exponentially weighted moving average* (EWMA) charts, and *change-point detection* (CPD) charts. Each class has its own strengths and weaknesses, and they can be implemented to assess different characteristics of systems or processes. Another classification of charts can be based on their distributional assumptions, leading to *parametric control charts* (PCC) and *nonparametric control charts* (NCC) [4]. PCC includes those charts designed or constructed based on assumed

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TABLE 1. Current applications of SPM Charts in healthcare.

Paper	Control Charts	Type of Charts	Purpose	Variables
Suman, G. & Prajapati, D. (2018)	• Shewhart-based Control Chart • EWMA • CUSUM • Multivariate Control Charts	• Parametric • Univariate & Multivariate	• Quality improvement assessment • Opportunity areas identification	• Infection rates • Number of patients • Mortality rates • Length of Stay (LOS) • Surgical errors
Slyngstad, L. (2021)	Shewhart-based control charts	• Parametric • Univariate	Quality improvement assessment	• Waiting time • Turnaround time • Operative time • Nonoperative time
Wolfe, H.A. et al. (2021)	Shewhart-based control charts	• Parametric • Univariate	Quality improvement assessment	• Average delay times • Medication errors (count and proportions)

probability distributions, with normality often being the assumed distribution. However, control charts with other probability models exist at their core [1]. When the distribution assumption is not met, the performance of the control chart (i.e., the ability to distinguish whether an event is IC or OC) can no longer be guaranteed. Based on the subdivision of methods by Conover depending on their underlying probability distribution assumption [5], it is considered as distribution-sensitive charts those whose performance heavily depends on fulfilling the distribution assumption. On the other hand, charts that exhibit good performance in their test statistic, even when the distribution assumption is not met, are considered distribution-robust charts. Furthermore, an NCC, or distribution-free control chart, maintains the same performance regardless of the true distribution of the data [4]. While some authors differentiate between nonparametric and distribution-free concepts, as suggested by Chakraborti and Graham [4] and Conover [5], we will use both terms interchangeably.

Initially developed for industrial applications, SPM control charts are now being applied in various fields, including the economy and healthcare. In healthcare, a collection of control charts for univariate and multivariate processes has been used for hospital management purposes and the assessment of quality improvement projects [2], [6], [7], [8], [9]. Table 1 provides an overview of common applications and control charts used in healthcare, as depicted in recent literature reviews. It is worth noting that most of the charts in Table 1 are parametric, which raises concerns regarding the assumption of data distribution. It is well-documented in the literature that real-world problems rarely conform to a specific probability distribution, and in many cases, the distribution is unknown. Consequently, misspecification of the parametric distribution can result in information loss and produce misleading or deceptive signals [4], [10], [11]. Furthermore, parametric control charts restrict monitoring to processes that follow the assumed probability distribution, leaving unattended areas in healthcare, such as biosurveillance and patient monitoring applications [2], [6]. To address these challenges and expand on recent reviews [7], [8], [9], which predominantly focused on PCC for hospital management and quality improvement assessment, the use of other monitoring schemes in SPM literature is suggested. One such approach is the utilization of nonparametric control charts (NCC), which do not rely on the assumption of a specific probability distribution and generalize the monitoring capabilities of the chart regardless of the true distribution of the data. Additionally, combining SPM with data-driven (DD) methods, such as popular machine learning models, can further enhance monitoring capabilities. By incorporating DD methods alongside control charts, a wider range of processes can be effectively monitored, surpassing the limitations of traditional SPM charts alone (See Section IV).

To the best of our knowledge, an extensive search of scientific literature in Scopus and Web of Science (WoS) revealed no existing review of nonparametric and DD approaches combined with SPM charts. As a result, there is a possibility that other healthcare areas, not covered in recent reviews, as well as important trends in SPM, may have gone unnoticed. To fill this gap and shed light on this emerging trend, this paper aims to search and synthesize current efforts in healthcare using nonparametric and DD approaches with SPM charts to create novel and synergistic monitoring schemes. This is achieved through a scientometric analysis of the retrieved papers and the classification of leading healthcare applications. By examining the scientific literature, we aim to identify and consolidate the existing knowledge in this field, thereby providing valuable insights into the application of nonparametric and DD approaches with SPM charts in healthcare.

This study aims to answer the following research questions through scientometric analysis and the results obtained from the classification of the retrieved papers:

- What are the current efforts, trends, and applications in healthcare where DD and nonparametric monitoring schemes are being used?
- Which existing research networks could scientists collaborate with to develop new ideas and methods to fill the gaps in healthcare monitoring using DD and nonparametric schemes?

- What are the potential gaps in current research that future studies could fill, thereby supporting future advancements in the field?

This review can be considered as an intersection between SPM, which has a tradition of model-driven approaches rooted in probability and statistics, and DD methods, which involve practical algorithmic assessment of data for various healthcare monitoring purposes. Readers from both areas might find value in the descriptions and discussions of the different methods that complement each other and allow for an expansion of the paradigm set. Control charts are powerful tools for monitoring systems, offering low computational costs. However, they have limitations in terms of data, structure, and frequency. In contrast, DD approaches might be perceived as computationally expensive, but they have the potential to enable or enhance the monitoring capabilities of control charts, thereby broadening the current scope of SPM. Simultaneously, SPM methods contribute as a sequential analysis framework that increases the power to detect changes when combined with DD techniques.

The remainder of the paper is presented as follows. Section II presents the methodology followed for paper retrieval. The summary results of the scientometric analysis are presented in Section III. Section IV explains the purposes of DD methods in SPM. Section V consolidates the literature classification based on healthcare applications. A discussion of the results and the trends for future research are presented in Section VI. Finally, conclusions and final remarks are in Section VII.

II. METHODOLOGY

This review aims to retrieve, classify, and analyze papers that present nonparametric or DD approaches using control charts for monitoring healthcare processes. To achieve this, two major scientific literature databases are consulted to accomplish the primary task of paper retrieval: Scopus and WoS. The search is limited to journal articles and conference papers published in the English language from the year 2000 onwards, ensuring a focus on recent advancements in the field. To construct an effective search query, three blocks of keywords are utilized: 1) SPM and control chart keywords, 2) healthcare keywords, and 3) DD and nonparametric keywords. The final version of the search query, divided by blocks, is presented in Table 2. The query syntaxes appropriate for Scopus and WoS are provided in Appendices VIII-A and VIII-B, respectively.

After retrieving the documents from both databases, a deduplication process was conducted, followed by manual validation to remove any unrelated articles. As a result, a total of 78 papers were retrieved. Among these, 15 papers presented NCC, 59 focused on DD approaches, and four both. Within the DD approaches, 51 papers proposed methods that use DD approaches before the monitoring process with a PCC (from now on, referred to as DD-before). Additionally, eight papers implemented DD approaches after the monitoring with a PCC (from now on, referred to as DD-after).

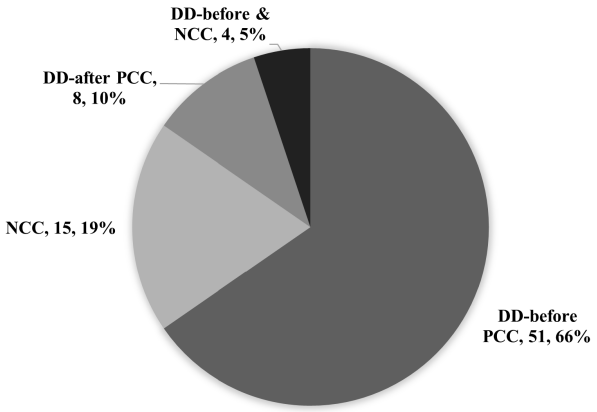

FIGURE 1. The count of documents based on the type of approach (NCC, DD-before PCC, DD-after PCC, or a combination of DD and NCC) proposed to monitor a healthcare process.

These findings are depicted in Fig. 1. Finally, a scientometric analysis and a classification based on the healthcare application were performed.

A. SCIENTOMETRIC ANALYSIS

Scientometrics analyzes a research topic by examining its quantitative features that describe its scientific production and trends [12]. Through the application of statistical methods, we can gather information that helps us understand the current landscape of the research topic. To achieve this, the yearly scientific production, as well as the top authors, journals, affiliations, and countries associated with the topic are identified. Additionally, the disciplines and categories based on the journal classification provided by WoS are retrieved to portray the primary areas of interest within the research topic and examine them across different regions of the world. Alongside, network maps of co-authorship and keyword co-occurrence were developed using the software Gephi.

This scientometric analysis aims to identify potential global research clusters to promote collaboration with other researchers and institutions to boost the current state-of-the-art of the topic at hand.

B. CLASSIFICATION OF DOCUMENTS

The retrieved papers are classified based on the healthcare application of the study. This classification aids the research trends identification process and is performed on each category individually. The following proposed categories are used:

1) Patient Monitoring: The process of following up on patients in a longitudinal study to assess their health status for a specific disease or based on a (set of) biomarker(s).
2) Pharmacology Monitoring: Related to the control of industrial processes in the pharmacology industry, focused on producing drugs and medicines.
3) Biosurveillance: Related to monitoring the dynamics of incidence counts of a specific disease in a geographically bounded space.

TABLE 2. Search query for DD approaches and NCC in healthcare.

Block	Keywords
SPM & Control Charts	Control Chart, Statistical Process Control, Statistical Process Monitoring, CUSUM Chart, EWMA Chart, Shewhart Chart, HWMA Chart, GWMA Chart, MEC Chart, Progressive Mean Chart, Synthetic Chart, Memory Type Chart, Profile Monitoring, Generalized Likelihood Ratio Chart, Multivariate Chart, Adaptive Chart, Variable Sample Size, Variable Sampling Interval, Changepoint Chart, Sequential Probability Ratio Test, Robust Chart, Bootstrap Chart, PCA Chart, Mahalanobis distance Chart, Runs Test, Tukey Chart, Rank-based Chart, Sign Chart, Signed Rank Chart, Mann Whitney Chart, Min Chart, Median Chart, Mean Rank Chart, Scale Rank Chart, k Chart
Healthcare	Healthcare, Health Science, Public Health, Private Health, Bioassay, Heart, Cardiac, Cardiology, Blood, Pediatric, COVID, Hormone, Endocrinology, Intestine, Entero-, Implant, Prosthetic, Tissue, Medic, Epidemiology, Biosurveillance, Hospital, Clinic, Patient, Physician, Emergency Room, Intensive Care Unit, Disease, Infection, Illness, Pathology, Syndromic Surveillance, Mortality, Morbidity, Forensic, Imaging, Radiology, Virus, Bacteria, Pancreas, Kidney, Pharmacology, Medic Drug, Psychology, Pandemics, Bone, Traumatology, Skin, Muscle, Surgery, Liver, Hepato-, Brain, Neurology, Lung, Pneumology, Cancer, Tumor, Carcinogenic, Biomaterial, Gastroenterology, Stomach, Immunology, Therapy, Biomedical
Data-driven & Nonparametric	Data-driven, Machine Learning, Artificial Intelligence, Decision Tree, Random Forest, Gradient Boosting, Support Vector Machine, Neural Network, Nearest Neighbor, Deep Learning, Partial Least Squares, Nonparametric, Distribution Free, Semiparametric

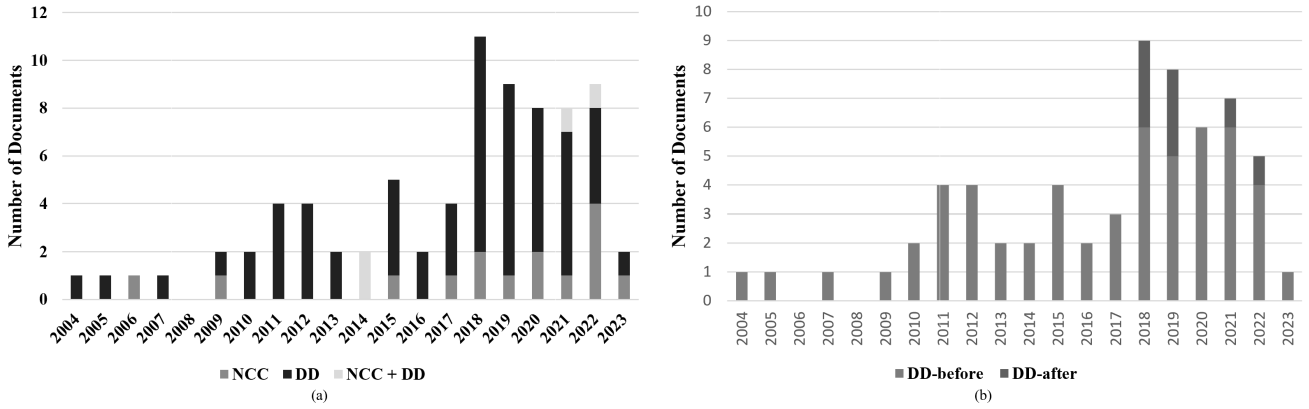

FIGURE 2. The growth kinetics of publication activity. (a) The annual number of documents published using an NCC, a DD approach in conjunction with a PCC, or both. (b) Differentiating papers published with a DD approach by year and whether they are DD-before or DD-after.

4) Hospital Management: Encompasses everything related to the management of a hospital (e.g., control of its finances, assessing customer support and experience, and managing internal databases).
5) Surgical Performance: Related to the degree of expertise of surgeons in performing a certain surgery in terms of surgery time, survival rate, or other metrics.
6) Bioassay Monitoring: Related to the monitoring of biological experiments in laboratories whose main purpose is intended for human health.
7) Medical Equipment Monitoring: The assessment of the proper operation of medical equipment.

This classification provides an overview of prevalent monitoring schemes in healthcare applications. It aims to identify trends, challenges, limits, and gaps in the current state of research. Furthermore, this information will offer insights into potential future work in the field.

III. SCIENTOMETRIC ANALYSIS RESULTS

Several quantitative metrics are obtained to perform the scientometric analysis of the research topic and portray its dynamics. These metrics are frequency summaries of documents published by year, authors, journals, countries, and affiliations, along with a journal classification to extract the main interests on the topic. The first metric is the growth kinetics of publication activity, which illustrates the popularity of the topic. As shown in Fig. 2.a, here is a positive trend in the publication rate of papers, with the most prolific year being 2018, with a total of 11 papers. Although the subsequent years (2019–2022) present a decrease in the number of published papers in this domain, we can still observe an overall growing trend. Each bar in Fig. 2.a is segmented based on the approach (i.e., NCC, DD approaches in combination with a PCC, and DD approaches in conjunction with an NCC) proposed in each paper. The most common proposals, based solely on the count of papers published on the topic, are DD approaches. Fig. 2.b is a zoomed-in view of the papers that present a DD approach in combination with control charts, whether parametric or nonparametric, dividing them into two classes: DD-before and DD-after approaches. From Fig. 2.b, it can be observed that DD-before approaches are the most common, exhibiting an increasing trend in literature. This result, as explained in more detail in Section IV, suggests that DD methods are frequently applied before the monitoring to

preprocess the data and enable its monitorability using SPM charts. On the other hand, DD-after approaches, although useful, remain less popular in comparison.

In the analysis of the most prolific authors, 274 are registered. Peihua Qiu from the University of Florida emerges as the leading author. The top 20 authors, those with more than one publication, are presented in Fig. 3.a. Moving on to journals and conferences, Fig. 3.b showcases the top journals and conferences with more than one paper. Out of 61 journals and eight conferences, only nine journals have published at least two related papers, with the top one being Medical Physics. This journal was ranked in 2021, according to Scimago JR, as Q1 in biophysics, medicine, and radiology, nuclear medicine and imaging, representing a benchmark in healthcare sciences. Figure 3.c displays the top affiliations involved in the research. A total of 130 affiliations are registered, with 101 being universities or academic research centers, 21 being companies (mostly pharmaceutical companies), five being hospitals, and three being governmental organizations (all located in the United States). The University of Florida stands out as a leading affiliation, with seven publications, aligning with the results of the top authors.

Next, WoS provides a classification of journals bsaed on the topics they cover. This classification comprises 21 disciplines with their corresponding categories (254 categories in total), which describe the scope and interests of each journal. Understanding the classification of a journal helps authors select the most suitable for their work and tailor their manuscripts to match the interests of the journal. Additionally, understanding the distribution of this classification among journals publishing papers on a specific topic helps to illustrate the primary interests of the scientific community regarding the studied subject. Fig. 4 illustrates the disciplines covered by this study and provides a breakdown of the top three ones (clinical medicine (20%), engineering (16%), and computer science (13%)). The combination of these three implies that research on this topic is the result of an interdisciplinary collaboration involving engineers using computer science methods, particularly DD methods, to monitor various topics in healthcare. This finding suggests that the focus of the research community is on monitoring new areas in healthcare that were not previously explored solely using PCC, with the addition of methods coming from other engineering disciplines.

Based on the geographical location of author affiliations, authors from 34 countries have contributed to this topic. In terms of document count, the United States takes the lead with 33 documents, followed by China with 11 documents, and the United Kingdom with six documents, as depicted in Fig. 5. To further explore the interests of different regions in the world (i.e., North America, Latin America, Europe, Asia, Africa, and Oceania) regarding the reviewed topic, the most frequent categories based on the journals' classification provided by WoS are identified. Generally, the most common categories are ''Statistics and Probability'' and ''Pharmacology and Pharmacy''. Additionally, categories related to computer science, such as ''Computer Science, Artificial Intelligence,'' and ''Computer Science, Others'' (including ''Artificial Intelligence,'' ''Information Systems,'' ''Software Engineering,'' and ''Theory and Methods'' for Africa, and ''Artificial Intelligence,'' ''Interdisciplinary Applications,'' and ''Theory and Methods'' for Oceania) are prominent. It is worth noting that Latin America remains an understudied topic in this field, with only one document from Brazil. These results are also visualized in Fig. 5.

In the network maps of co-authorship and keyword co-occurrence, the size of the nodes and text increases with the frequency of co-occurrence, indicating the prominence of certain authors or keywords. The width of the edges corresponds to the number of times two elements have co-occurred. Also, the darkness of the color represents the weight of an edge or node, suggesting the strength or significance of the connection. In the co-authorship map (Fig. 6), mainly individual clusters are observed, with almost one cluster per paper, and a few clusters present connections between them. This indicates that most authors tend to publish only one paper related to the topic and have limited collaboration beyond their existing co-author circle.

For the keyword co-occurrence map, the selected keywords by the authors are used and filtered to identify the most frequently occurring ones. During the filtering process, keywords that appear only once are removed. The map focuses on the edges where words co-occur in the retrieved papers at least twice, and unconnected nodes are eliminated. Fig. 7 displays two clusters. The cluster on the left side presents keywords related to the pharmacology monitoring category. This cluster illustrates the common strategy of using control charts combined with DD methods for monitoring applications in pharmacology. The cluster on the right side, centered around the main keyword ''statistical process control,'' portrays the most popular applications of SPM in healthcare (e.g., ''disease surveillance,'' ''online monitoring,'' ''early detection,'' and ''dynamic screening'') and common strategies that let the user monitor a healthcare application (e.g., ''data decorrelation,'' ''unequal sampling intervals,'' ''nonparametric methods,'' and ''longitudinal data'').

IV. DATA-DRIVEN METHODS

This section presents a summary and explanation of the DD methods to help understand the approaches proposed by the analyzed documents. DD methods are combined with control charts for various reasons, but they all converge to improve the monitoring capabilities of SPM charts. The analysis of the papers identified seven purposes for the applications of DD methods. In some cases, DD methods serve more than one purpose (i.e., variable selection, confidence interval computation, and baseline model estimation). Among these purposes, four are used with DD-before, one for DD-after, and two for both DD approaches. The different purposes, listed in order of their frequency in the literature, are as follows: 1) baseline model estimation (40 docs.), 2) response prediction (8 docs.), 3) data classification (5 docs.), 4) feature extraction (4 docs.),

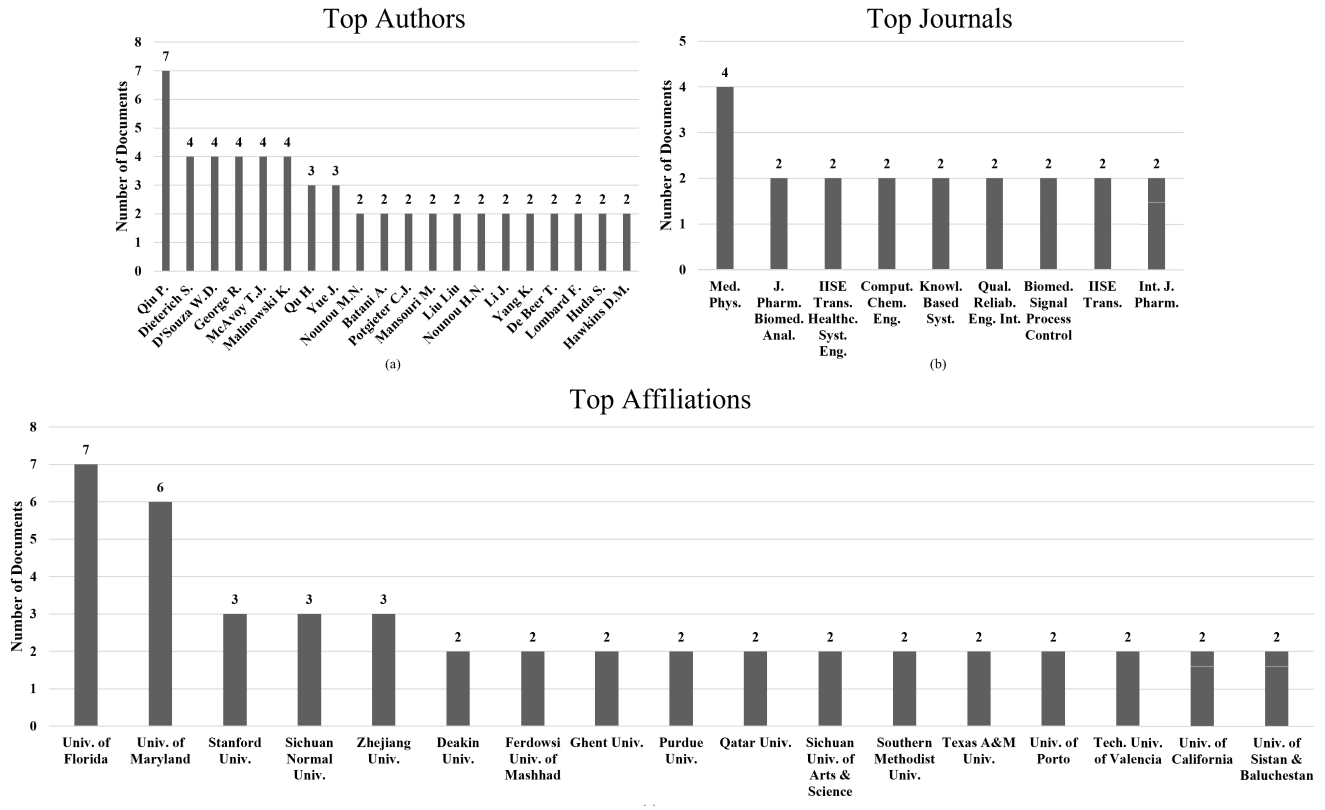

FIGURE 3. Most prolific (a) authors; (b) journals; and (c) affiliations in reviewed papers.

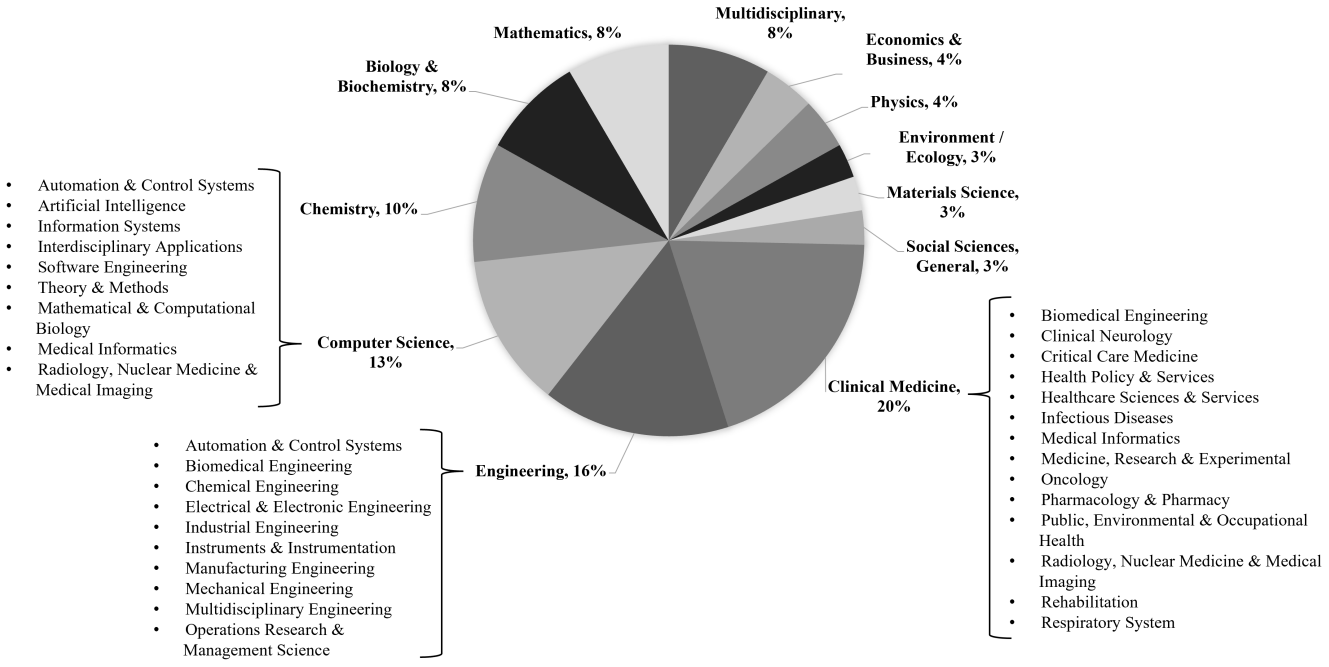

FIGURE 4. Disciplines covered by journals publishing the reviewed papers and the breakdown of the top three of them.

5) post-signal diagnosis (4 docs.), 6) confidence interval computation (3 docs.) and 7) variable selection (1 doc.).

Each purpose is used differently to improve the monitoring process that a control chart alone can achieve. A graphical

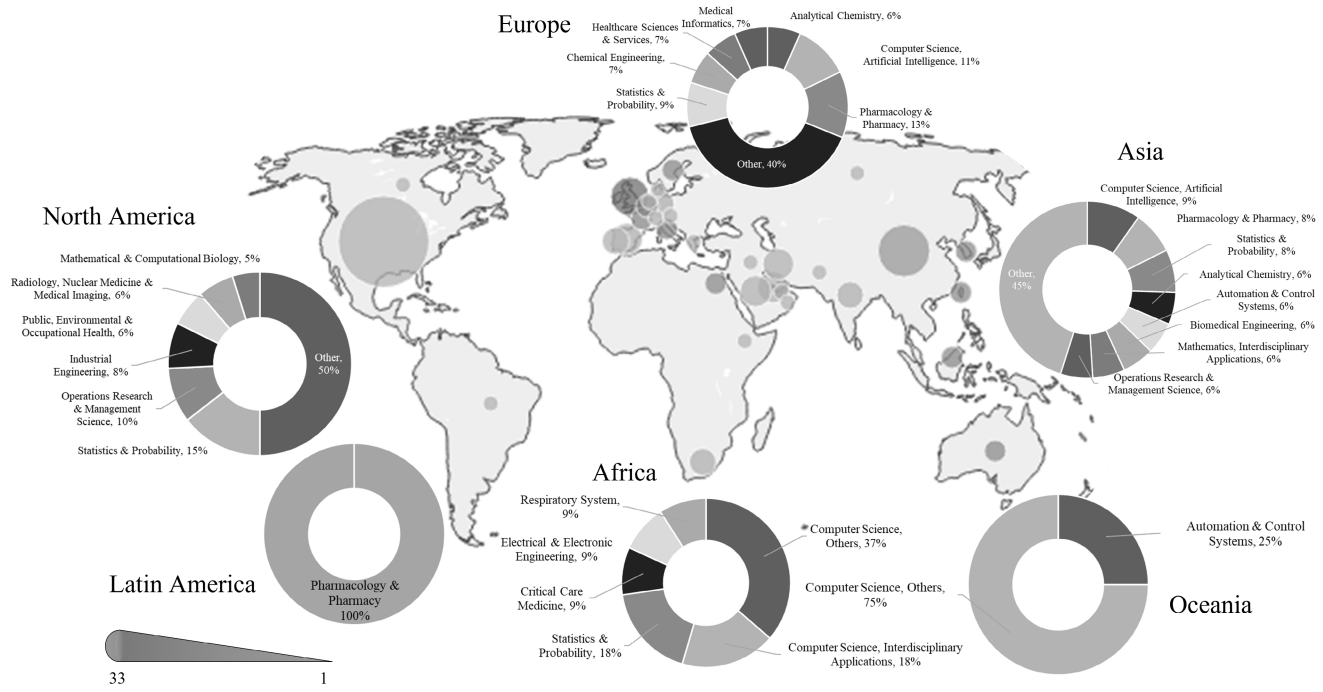

FIGURE 5. Bubble world map of documents published by country, along with the distribution of categories based on journals' classification by world region (i.e., North America, Latin America, Europe, Asia, Africa, and Oceania).

representation of the purpose of each DD method is depicted in Fig. 8, where the main steps and the flow of the approach are illustrated. The improvements achieved are as follows:

Baseline model estimation is utilized to model process variables using a mathematical function that includes the principal effect of variables and their interactions as they change from a predefined probability distribution [13]. Additionally, these DD methods are built to address characteristics commonly found in healthcare applications, such as heterogeneity between subjects, time correlation, and dynamic IC profiles, also known as profile monitoring in the SPM literature [1], [14]. The resulting baseline and coefficients obtained for each variable are monitored using a control chart. Several DD approaches were found to fit the input variables. Some of these are variants of partial least squares (PLS) [15], [16], [17] or kernel smoothing [14], [18], [19] via an optimization algorithm that assigns a coefficient to each variable, allowing the prediction of future samples.

Response prediction consists of predicting the response of a fitted model built with a DD method trained from a history of process variables. This response is evaluated against the observed value to estimate the residual at each monitored time. A function of these residuals is then assessed with a control chart [13]. This category fits inside the baseline model estimation. However, proposals classified under response prediction cannot be used for profile monitoring since the only relevant output for monitoring is the response itself as a forecast or index that summarizes the effect of one or more input variables. For profile monitoring purposes, not only the output but also the model structure are relevant to monitor the sequential evolution of all variables involved in the studied process, which is not the case for the proposals under this category where the model structure is intractable. Such is the case of black box approaches related to neural networks (NN) [20], [21], [22], [23], decision trees [24], [25], and support vector machines (SVM) [26], [27].

Before process monitoring, **data classification** is used to identify groups or clusters of data with common characteristics that can be used for supervised work. It builds a control chart with the ''normal'' data and tests it with the ''abnormal'' one. For instance, this approach is used to fit an ensemble model consisting of several classifiers (e.g., random forest, bagging, and AdaBoost) for disease occurrence monitoring [28] or a k-Nearest Neighbor method for a batch-to-batch drug monitoring [29]. In addition, data classification can be used after the monitoring process to further classify the OC event under a predefined label established by the user. For instance, in Hassan et al. [30], the OC event is fed to an AdaBoost classifier trained to determine if the shift in the variables signifies a positive or negative diagnosis for a particular disease.

Feature extraction is employed to obtain monitorable variables from the observed raw signals of a process. It might follow a classification process [31], [32], a geometrical transformation or signal decomposition [33], [34]. One example is extracting features when a heartbeat happens in an electrocardiogram (ECG) by identifying the R-peak using a wavelet function [34]. This method denoises the biosignal by

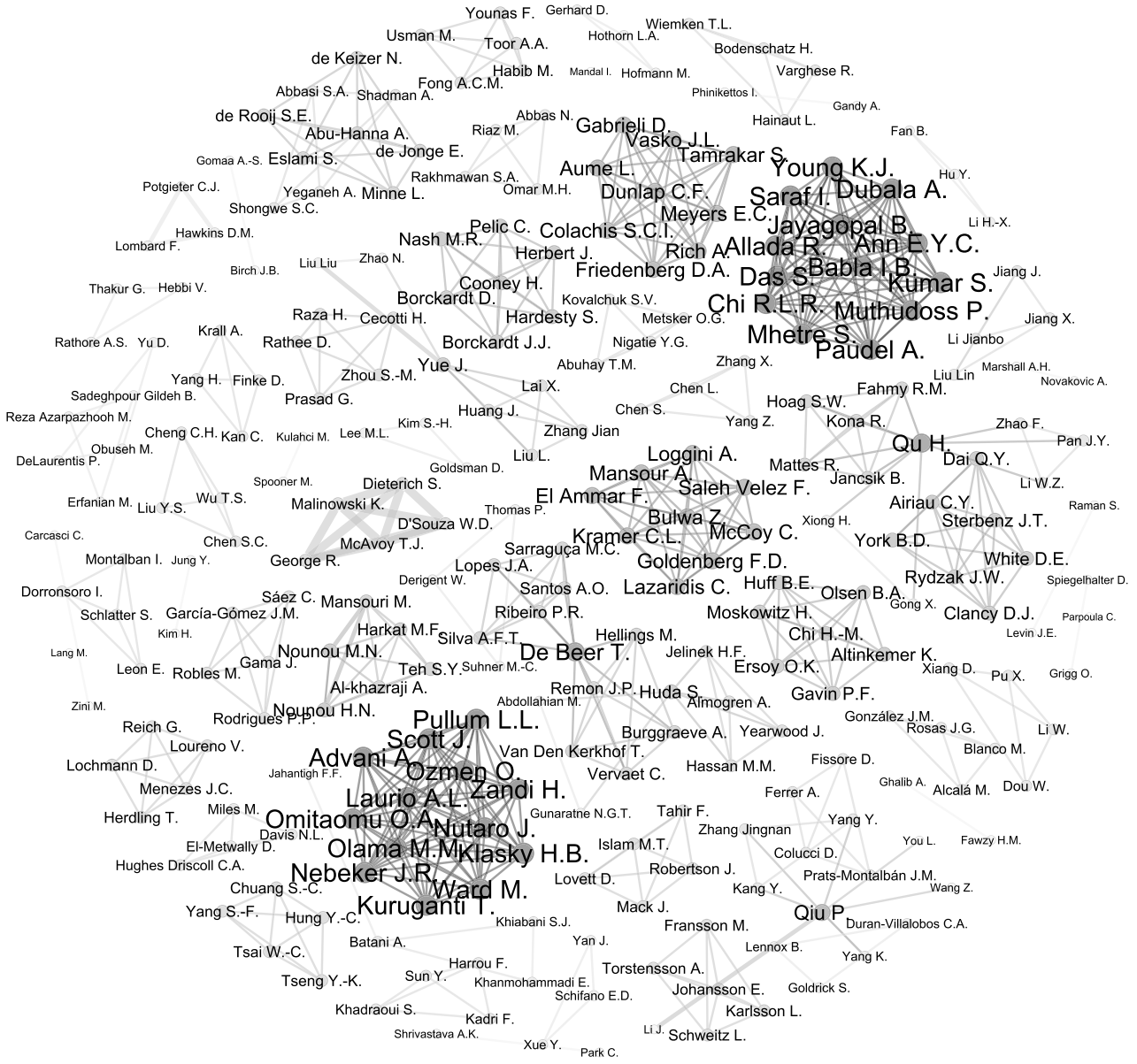

FIGURE 6. **Co-authorship network map.**

smoothing it and detecting when the highest peak, which indicates the ventricular contraction of the heart, occurs. A control chart can be constructed using normal beats and tested with abnormal ones with this information.

After an OC signal is triggered during a monitoring process, **post-signal diagnosis** is used with a multivariate control chart to identify the responsible variables. Unlike a univariate process, where the OC event is directly related to the monitored variable, the charting statistic in a multivariate control scheme summarizes the effect of all involved variables in one value. This creates difficulty in detecting which variables are in charge of the shift [35], [36]. Therefore, extra aid is needed. One example is implemented in Loggini et al. [37], where a decision tree is trained to find a set of simple rules for variable selection, performing a binary split of the data that separates subjects into normal (IC) and abnormal (OC), and producing an explainable model, where variables selected are the ones considered to be responsible for the OC events.

Confidence interval computation enables the computation of the control limits that a control chart will employ to discriminate between IC and OC. It is especially used when the process does not follow a defined probability distribution [13]. The most common DD method is re-sampling, whether used to set up a control chart [38] or applied afterward to update limits [39]. Bootstrap, a popular re-sampling technique, takes a sample of size n from the original sample of

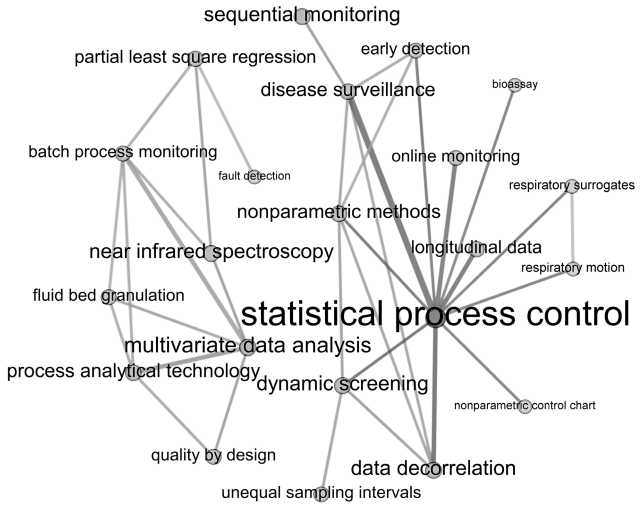

FIGURE 7. Keyword co-occurrence network map.

the same size, with replacement, and calculates the charting statistic to create an artificial history of events. This estimates the cumulative distribution function (CDF) of the charting statistic, which is used to set control limits based on the desired error level (also referred to as α).

Variable selection weighs variables of a process based on their participation in the observed response. It makes it possible to discard non-significant variables to reduce the set to a smaller number of explanatory variables capable of representing and explaining the process behavior [40]. An example is Erfanian et al. [41], where a subset of variables is selected by applying a backward stepwise logistic for a *generalized additive model* (GAM). The model starts by fitting all variables and obtaining their corresponding p-values and the associated measure of the *Akaike Information Criterion* (AIC). Then, the non-significant variables, $p > 0.05$, are removed, and the model has fitted again. The process is repeated until the number of significant variables generates the smallest AIC. Afterward, multivariate control charts are built to monitor the process with the subset of variables. This step is critical for high-dimensional processes since multivariate control charts can only manage up to a dozen variables [42] before their power is reduced too much.

V. RESULTS OF THE CLASSIFICATION OF DOCUMENTS

As described in Section II-B, the selected papers are classified into seven categories based on the healthcare application. These categories are listed in descending order according to the number of classified documents, including: 1) patient monitoring (28 papers), 2) pharmacology monitoring (16 papers), 3) biosurveillance (15 papers), 4) hospital management (11 papers), 5) surgical performance (five papers), 6) bioassay monitoring (two papers), and 7) medical equipment monitoring (one paper).

The following subsections provide a detailed review of each category, including a list of the specific healthcare applications, the type of control chart used in the approach (i.e., DD, NCC, or a combination), the number of variables considered (univariate or multivariate), and the type of DD methods used and their purposes. This will allow researchers and companies to identify and pinpoint trends that can aid in proposing new research topics or changing their focus.

A. PATIENT MONITORING

As shown in Fig. 9.a-c, a variety of control chart methods are proposed for patient monitoring, which is grouped into six general classes: 1) patient safety & survival, 2) disease occurrence monitoring, 3) biomarker monitoring, 4) disease occurrence monitoring, 5) *electrocardiogram* (ECG) monitoring, and 6) *electroencephalogram* (EEG) monitoring. It is important to clarify that the term "multivariate" does not imply the use of a multivariate control chart. Instead, it means that the analyzed process is multivariate. In certain control charts, the most relevant feature after a *principal component analysis* (PCA) [43], or the difference between the observed value and the predicted response [20], [21], [22], [44], [45], is controlled.

The most common purpose of using a DD-before approach (13 out of 19 documents) is to estimate a baseline model, which allows monitoring of a process by modeling an IC function that encompasses its normal behavior. As cdiscussed later in this paper, this is the case for most categories. Additionally, DD-before methods are used for feature extraction from complex biosignals (e.g., ECG and EEG) as demonstrated in [33] and [34]. On the other hand, DD-after approaches are utilized for tasks such as data classification, post-signal diagnosis, and confidence interval computation. The complete summary of the documents classified under this category is presented in Table 3.

Two trends are spotted in the documents that employ a DD-before approach. In both trends, the DD method estimates a baseline model, which enables the monitoring of the healthcare process using a univariate control chart. The distinction between the two trends lies in the charting statistics calculated from the baseline. In the first group of papers [20], [21], [22], [44], [45], [46], and [47], the residuals are computed by taking the difference between the baseline model prediction and the observed online value. These residuals are then accumulated using a univariate memory-based control chart (e.g., EWMA, CUSUM, and a variation of the GLR chart with exponential weights). In the second group of papers, the deviation from the baseline (i.e., a distance) is calculated and monitored using either a k chart [48] or a variation of the *Double*-EWMA (DEWMA) chart using the sum-square approach in the charting statistic equation [49].

This category presents limitations and challenges that may result in incorrect modeling or monitoring of a process:

- The correct modeling of the time series behavior depends on the complex characteristics of the data (e.g., dynamic IC distributions and temporal autocorrelation).
- They must be adjusted or retrained to monitor other diseases or patients with different phenotypic and genotypic backgrounds.

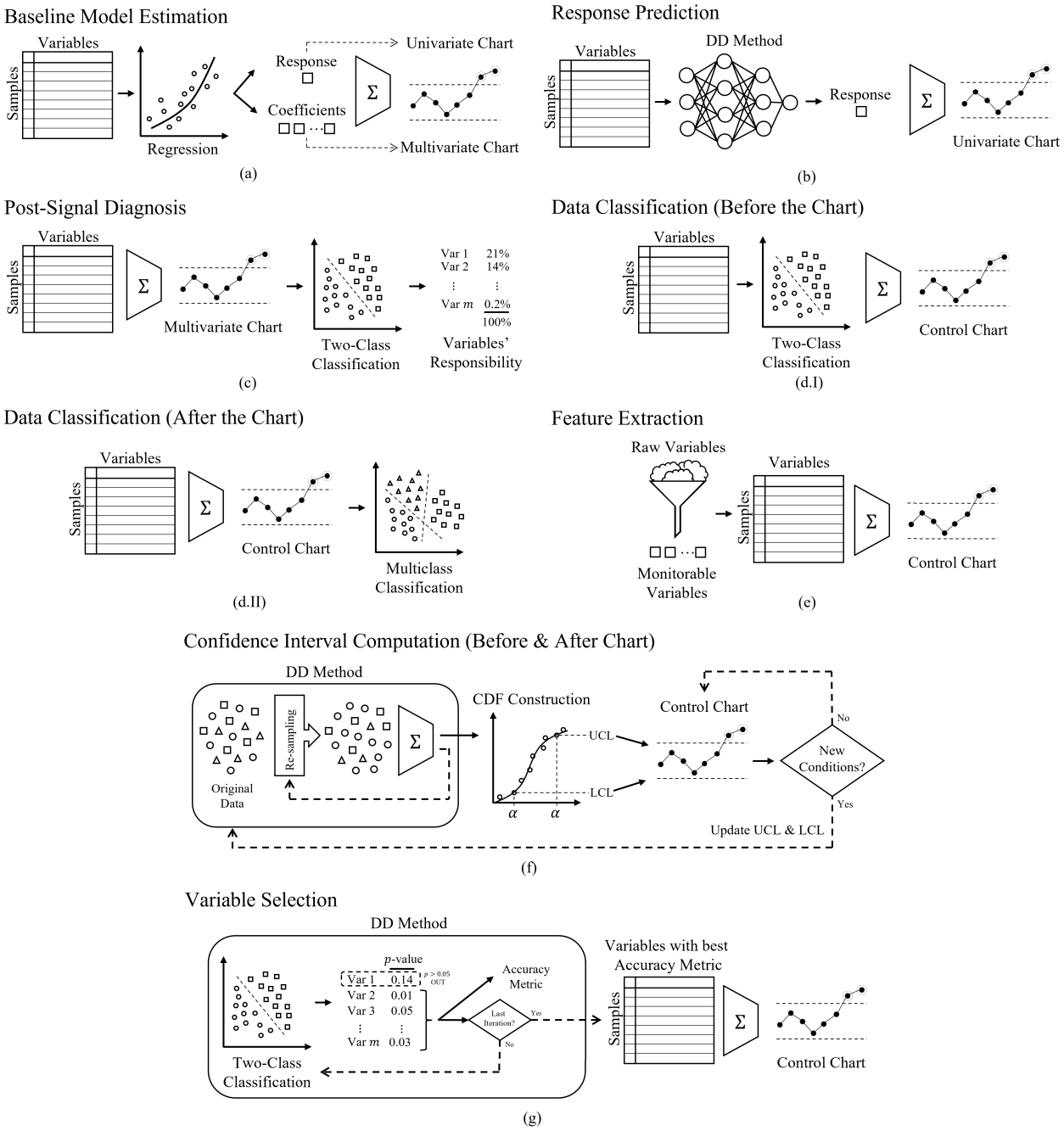

FIGURE 8. Data-driven method classification. The trapezoid with the uppercase sigma letter represents the calculation of the corresponding charting statistic.

- Data scarcity and quality are hard to handle since the available healthcare-related datasets usually have fewer subjects than an industrial dataset.

Finally, three gaps are identified that could be addressed in future research:

- Normality is assumed for the monitored residuals with PCC, but it is not tested, or at least not shown in the text; hence, the performance of the PCC in terms of the false alarm rate could be compromised.
- Timeseries in multivariate processes could be misaligned in the observation times (e.g., hourly, daily, weekly, etc.) they present, disabling the monitoring with off-the-shelf designs of SPM charts.
- Comparisons with other DD-based proposals are usually missing, leaving room for doubt as to whether the proposal is better than others already published.

B. PHARMACOLOGY MONITORING

This category presents documents that propose using NCC alone or DD-before in combination with a PCC or an NCC (see Fig. 9.d). Among the papers with DD implementation, 13 out of 14 papers, the most repeated application uses DD

TABLE 3. Patient Monitoring documents overview.

General Application	Application	Chart	# Variables	Type	DD Method	DD Method Purpose	References
Patient Safety & Survival	Length of Stay (LOS) in Intracerebral Hemorrhage (ICH) Patients Monitoring	CUSUM	Univariate	DD After	Decision Tree	Post-signal diagnosis	Loggini et al. [37]
	Inhaled Nitric Oxide in NICU Monitoring	Wilcoxon Rank Sum Shewhart	Univariate	NCC	N/A	N/A	Hughes Driscoll et al. [84]
	Patient's Hospital Stay after a Stroke Episode Monitoring	CUSUM	Univariate	DD Before & NCC	Kaplan Meier Estimation	Baseline Model Estimation	Phinikettos & Gandy, [85]
	Tumor Motion Monitoring	Hotelling's T^2 & Q Chart	Multivariate	DD Before	Partial Least Squares (PLS)	Baseline Model Estimation	Malinowski et al. [86] Malinowski et al. [87] Malinowski et al. [88] Malinowski et al. [89]
ECG Monitoring	Blood Pressure Monitoring	EWMA	Multivariate	DD Before	Perceptron Neural Network	Response Prediction	Khiabani et al. [20]
	ECG Monitoring	k Chart	Multivariate	DD Before & NCC	Support Vector Machine (SVM)	Baseline Model Estimation	Chen et al. [48]
		Hotelling's T^2 Chart	Multivariate	DD Before	Network Modeling	Baseline Model Estimation	Yang et al. [90]
		Hotelling's T^2 Chart	Multivariate	DD Before	Wavelet Transformation	Feature Extraction	Jung & Kim, [34]
	ECG & Photoplethysmographic (PPG) Monitoring	CUSUM	Univariate	DD Before	Singular Spectrum Analysis (SSA)	Feature Extraction	Lang, [33]
Biomarker Monitoring	Acrophase (maximum systolic blood pressure in a day) Monitoring	CUSUM	Univariate	NCC	N/A	N/A	Lombard et al., [91] Lombard et al. [92]
	Total Cholesterol Monitoring in Stroke Patients	EWMA	Multivariate	DD Before	Local Linear Kernel Smoothing (LLKS)	Baseline Model Estimation	Li et al. [45]
	Troponin Monitoring	CUSUM	Univariate	DD After	Bootstrap	Confidence Interval Computation	Abuhay et al. [39]
	Heart Indices Monitoring	EWMA	Multivariate	DD Before	Multilayer Perceptron (MLP) Neural Network	Response Prediction	Jahantigh & Batani, [21]
	Systolic Blood Pressure Monitoring	CUSUM	Univariate	DD Before	Local Polynomial Kernel Estimation (LPKE)	Baseline Model Estimation	Li & Qiu, [47]
Disease Occurrence Monitoring	Colonoscopy Video Stream Monitoring	EWMA	Multivariate	DD Before	Chebyshev's Polynomial Approximation	Confidence Interval Computation	Toor et al. [95]
	Stroke Cases Monitoring	EWMA	Multivariate	DD Before	Cox Proportional Hazards Model	Baseline Model Estimation	You & Qiu, [44]
		MEWMA	Multivariate	DD Before	Local Linear Kernel Smoothing (LLKS)	Baseline Model Estimation	Li & Qiu, [76]
Disease Occurrence Monitoring	Genetic Copy Number Data Monitoring	EW-GLR Chart	Univariate	DD Before	Multiscale Kernel Partial Least Squares (MKPLS)	Baseline Model Estimation	Mansouri et al. [46]
		DEWMA	Univariate	DD Before	Multiscale Wavelet Decomposition	Baseline Model Estimation	Mansouri et al. [49]
	Cardiovascular Autonomic Neuropathy (CAN) Diagnosis Monitoring	MEWMA	Multivariate	DD After	AdaBoost	Data Classification	Hassan et al. [30]
	Spinal Cord Injury Monitoring	X Chart	Univariate	DD Before	Ensemble Model	Data Classification	Mandal, [28]
EEG Monitoring	BCI Channels Monitoring	X & S Chart	Univariate	DD After	Long Short-Term Memory (LSTM) Neural Network	Data Classification	Vasko et al. [93]
	Covariate Shifts Monitoring in an EEG-based BCI system	EWMA	Multivariate	DD After	Probabilistic Weighted K Nearest Neighbor (PWKNN)	Data Classification	Raza et al. [43]
	Emotions Monitoring	CUSUM	Multivariate	DD Before	Auto-Associative Neural Network (AANN)	Response Prediction	Leon et al. [22]

methods to generate a baseline model estimation, usually choosing the PLS method or one of its variants (see Table 4).

As depicted in Fig. 9.e, most implementations are multivariate; however, monitoring is often conducted with univariate charts. Similar to the scenarios in Sec. V-A, two approaches are prevalent: monitoring of the most relevant variables [15], [50], [51], [52] or monitoring of their residuals [17].

Pharmacology monitoring encompasses various applications, including freeze-drying, protein PEGylation, hot-melt extrusion, drug crystallization, fluid bed granulation, liquid-liquid extraction, gel manufacturing process, liquid chromatography process, and fermentation process. These applications are closely related to reliable manufacturing, where products, as opposed to patience-to-patience monitoring, are homogeneous in nature, allowing for tighter

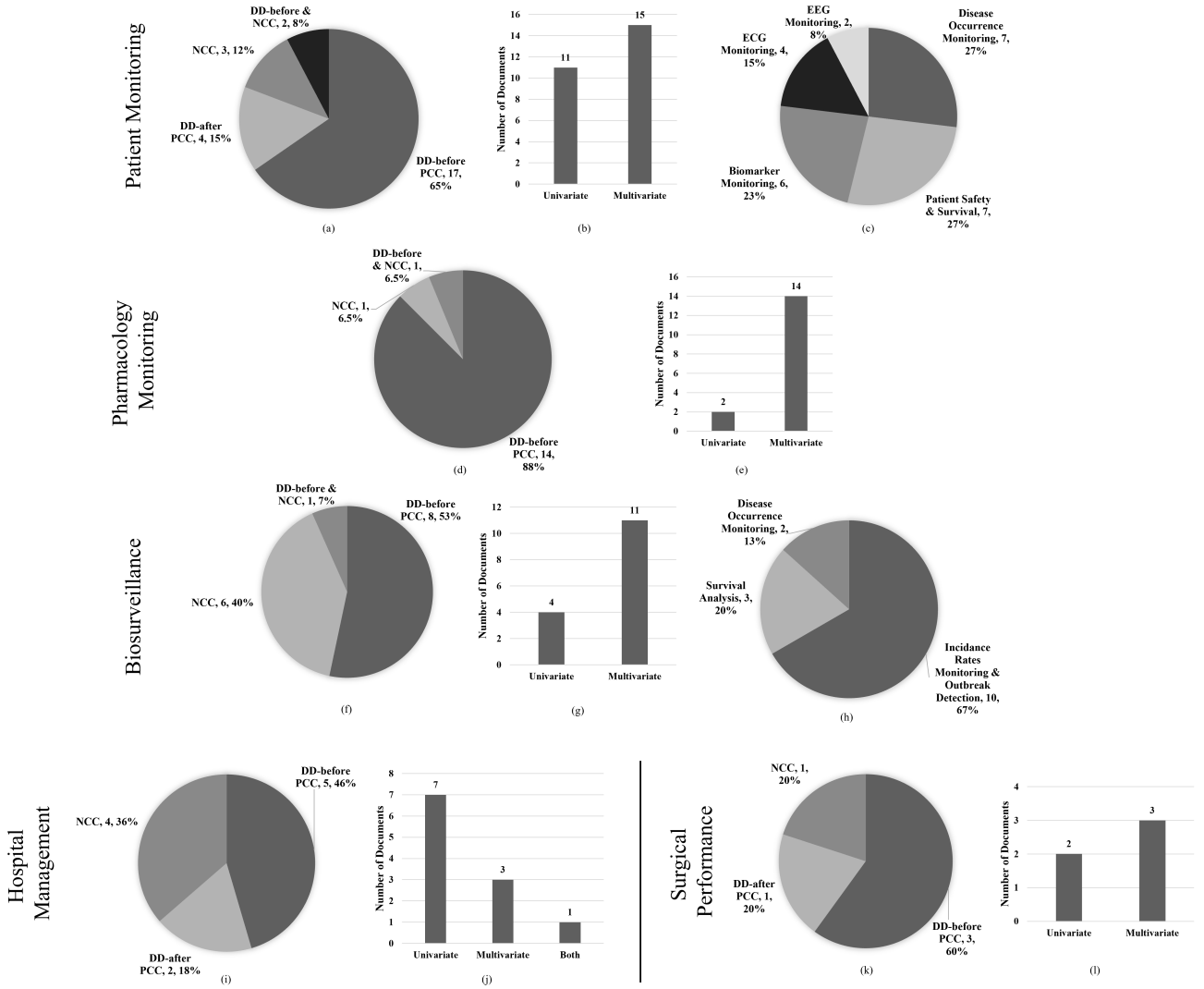

FIGURE 9. An overview of healthcare applications in patient monitoring: (a) the proposed approach, (b) number of variables monitored, and (c) application type; in pharmacology monitoring: (d) proposed approach, and (e) number of variables monitored; in biosurveillance: (f) the proposed approach, (g) number of variables monitored, and (h) application type; in hospital management: (i) the proposed approach, and (j) number of variables monitored; and in surgical performance: (k) the proposed approach, and (l) number of variables monitored.

tolerance limits and high reliability. Consequently, the control charts typically employed are parametric methods with conventional control limits set at ± 3 standard deviations. The usual way to control these processes follows the idea of batch-to-batch monitoring, where observations are collected and plotted on a control chart each time a sample is obtained.

A trending strategy using the DD-before approach involves dimensionality reduction. In particular, PLS or one of its variants is used to monitor selected components. An example of monitoring scores derived from the PLS model is the use of Hotelling's T^2 chart in combination with a control chart for monitoring the *Squared Prediction Error* (SPE). Common choices for control charts in this context include the Q chart [15], [16], [51], [52], [53], [54], [55], [56], [57], [58], X-bar charts [51] and X-charts [15], [17], [50], [52], [59].

The limits and challenges identified for this category align with traditional limits and challenges found in SPM literature, for instance:

- Batch production reduces the monitoring horizon to a finite size, where calibration for a finite horizon production can reduce error and increase detection power.
- The accurate modeling of complex characteristics of time-series data, such as stationarity, outliers, and temporal autocorrelation, is often overlooked.
- The curse of high dimensionality, arising from a large number of samples and variables, is prevalent in this industrial context due to the high volume of products and the abundance of data-collecting sensors.

The following gaps are identified:

- The usual monitoring scheme used is PCC, but the probability distribution of the data is not tested; hence, the use of NCC or other DD-based charts could improve the monitoring performance in these applications.
- While using ± 3 standard deviations as control limits for SPM charts is considered the gold standard, it may be

TABLE 4. Pharmacology Monitoring documents overview.

Application	Chart	# Variables	Type	DD Method	DD Method Purpose	References
Herbal Medicine Reflux Extraction Monitoring	X, Hotelling's T^2 & Q Chart	Multivariate	DD Before	Partial Least Squares (PLS)	Baseline Model Estimation	Li et al. [15]
Active Pharmaceutical Ingredient (API) Measure Monitoring	Bootstrap (p Chart like)	Univariate	NCC	N/A	N/A	Muthudoss et al. [96]
Protein PEGylation Monitoring	X & Q Chart	Multivariate	DD Before	Multivariate Partial Least Squares (MPLS)	Baseline Model Estimation	Hebbi et al. [50]
Freeze-Drying Process Monitoring	Hotelling's T^2 & Q Chart	Multivariate	DD Before	Partial Least Squares (PLS)	Baseline Model Estimation	Colucci et al. [53]
Fermentation Process Monitoring	Hotelling's T^2 & Q Chart	Multivariate	DD Before	Multiway Partial Least Squares (MPLS)	Baseline Model Estimation	Duran-Villalobos et al. [16]
Hot-Melt Extrusion Monitoring for Drugs Production	X Chart	Multivariate	DD Before	Partial Least Squares (PLS)	Baseline Model Estimation	Tahir et al. [17]
Penicillin Batch Monitoring	Distance Chart	Multivariate	DD Before & NCC	K-Nearest Neighbors	Data Classification	Spooner & Kulahci, [29]
Drugs Crystallization Monitoring	Hotelling's T^2 & Q Chart	Multivariate	DD Before	Orthogonal Partial Least Squares (OPLS)	Baseline Model Estimation	Silva et al. [54]
	X Chart	Univariate	DD Before	Support Vector Regressor (SVR)	Response Prediction	Chi et al. [27]
Oligonucleotides Synthesis Monitoring	Hotelling's T^2 & Q Chart	Multivariate	DD Before	Partial Least Squares (PLS)	Baseline Model Estimation	Rydzak et al. [55]
Fluid Bed Granulation Monitoring	Hotelling's T^2 & Q Chart	Multivariate	DD Before	Partial Least Squares (PLS)	Baseline Model Estimation	Kona et al. [56]
	X & Hotelling's T^2 Chart	Multivariate	DD Before	Multiway Partial Least Squares (MPLS)	Baseline Model Estimation	Loureno et al. [52]
	X Chart	Multivariate	DD Before	Partial Least Squares (PLS)	Baseline Model Estimation	Burggraeve et al. [59]
Liquid-Liquid Extraction Monitoring	X, Hotelling's T^2 & Q Chart	Multivariate	DD Before	Multiway Partial Least Squares (MPLS)	Baseline Model Estimation	Xiong et al. [51]
Gel Manufacturing Process Monitoring	Hotelling's T^2 & Q Chart	Multivariate	DD Before	Multiway Partial Least Squares (MPLS)	Baseline Model Estimation	Rosas et al. [57]
Liquid Chromatography Process Monitoring	Hotelling's T^2 & Q Chart	Multivariate	DD Before	Partial Least Squares (PLS)	Baseline Model Estimation	Schweitz et al. [58]

beneficial to consider tailor-made control limits that are more appropriate for specific situations.
- Temporal autocorrelation is typically disregarded in these applications; hence, the use of data decorrelation techniques could be explored.
- The use of a hybrid variable selection strategy that combines dimensionality reduction algorithms with experts' opinions has the potential to enhance the monitoring performance of SPM charts.
- The use of finite horizon modeling instead of assuming an infinite production for pharmacology monitoring applications could be more adequate.
- The comparison with other proposals could help researchers identify the best monitoring approaches in this category.

C. BIOSURVEILLANCE

Papers in this category can be divided into three groups based on the type of monitoring: 1) implementing the DD-before approach combined with a PCC, 2) monitoring with an NCC, and 3) monitoring with a combination of DD-before and an NCC (Fig. 9.f). When selecting a DD method, baseline model estimation tops the list of use cases.

As seen in Fig. 9.g), the applications in this category encompass both multivariate and univariate scenarios. In multivariate processes, monitoring is typically conducted using a univariate control chart by considering either the residuals [14], [19] or the resulting distance between the observed value and the model constructed using the DD method [38].

Based on their application, biosurveillance can be further categorized, as seen in Fig. 9.h, into incidence rate monitoring & outbreak detection, survival analysis, and disease occurrence monitoring. Analyzing Table 5 reveals that, for all univariate processes within the incidence rate monitoring & outbreak detection group, only the temporal effect (i.e., samples at different time points) is taken into account for monitoring, while the spatial effect (i.e., samples at different geographical locations) is neglected.

When considering the method, two main trends are identified. First, whenever there is a DD-before approach, the DD method is used, except in two cases, for baseline model estimation. The specific DD method used varies, but the most common technique is kernel smoothing in combination with an algorithm to address temporal decorrelation (e.g., the AR model, Cholesky decomposition, and ARIMA model) along with a univariate memory-based control chart (e.g., EWMA and CUSUM) [14], [19], [60]. Secondly, the standardized sequential rank statistic is the most commonly implemented nonparametric transformation. It is used for monitoring a disease with a MEWMA Chart [61], [62], where Liu et al. [62] enhance the approach by incorporating an AR model to decorrelate the data and obtain a baseline model for monitoring.

Some limits and challenges are identified:

- Lack of genericity, as the monitoring methods may not be applicable to every disease or geographical location.
- Data quality could improve the model accuracy by focusing on incidence rate and including other clinically relevant variables and biomarkers.
- Accurate modeling of time-series behavior is important, and techniques such as ARIMA or its variants can be used to address model misspecification.

The gaps identified for this category are the following:

- The robustness of memory-based PCC could be insufficient, and exploring monitoring approaches with NCC or DD-based charts that do not rely on distributional assumptions could be beneficial.
- The comparison with other proposals could help researchers identify the best monitoring approaches in this category.
- It is important to optimize the hyperparameters of DD methods as a common practice to ensure the best monitoring design for the specific process.

D. HOSPITAL MANAGEMENT

The category of hospital management is broad in terms of the variety of applications, with a lean toward service and transactional operations. Based on the monitoring approach, three main categories can be distinguished: 1) DD-before combined with PCC, 2) NCC, and 3) the DD-after with PCC (see Fig. 9.i). Furthermore, the category includes proposals with different numbers of variables, including univariate, multivariate, and even a combination of both (Fig. 9.j). In cases where a multivariate process is monitored with a univariate chart, the monitoring is typically focused on a response variable from a model, as demonstrated in the works of Minne et al. [25] and Zini & Carcasci [101], or using a proportion with a p-chart [63].

The papers in the hospital management category can be further divided based on their approach: 1) DD-before, focusing on baseline model estimation and response prediction, and 2) DD-after, involving post-signal diagnosis. While the monitoring is performed on a single variable, such as counting cancellations or medical expenses, several potential explanatory variables are examined to explain an observed out-of-control signal. Characteristics of papers under this category are given in Table 6.

Due to various applications and approaches, detecting a specific trend in this category is difficult. Nevertheless, it is worth noting that the processes and approaches in this category are closely related to SPM research in traditional quality engineering schemes. In several cases, variables monitored are counts, proportions, or raw measures evaluated with a Shewhart-type chart with the usual ± 3 sigma limits. TMore detailed information on this topic can be found in the reviews by Suman & Prajapati [7], Slyngstad [8], and Wolfe et al. [9].

The following limits and challenges were identified:

- The curse of high dimensionality is attributed to the varied applications in this category.
- The misspecification of the hyperparameters of DD methods increases the likelihood of obtaining a suboptimal model or overfitting.
- Correctly modeling time-series behavior is complicated because of its complex structure (e.g., stationarity, outliers, and temporal autocorrelation).

The gaps for this category are as follows:

- Normality is assumed for the monitored residuals with PCC but not tested; thus, the reported performance of PCC could be incorrect.
- The probability distribution of the data is not tested, and a parametric distribution is assumed; hence, the use of NCC or other DD-based charts could improve the monitoring performance in these applications.
- The current proposal could benefit from using a data decorrelation technique to alleviate the effect of temporal autocorrelation present in these processes.
- The comparisons with other proposals and hyperparameter optimization are lacking, resulting in the possibility of presenting a non-optimal model.

E. SURGICAL PERFORMANCE

As shown in Fig. 9.k, the papers in this category belong to the monitoring with DD-before and DD-after with PCC, as well as monitoring with an NCC. Approaches with DD-before techniques were applied to estimate a baseline function or to predict a response based on process variables, while also considering subjects' heterogeneity and the dynamic IC functions of the analyzed variables. DD-after approaches were implemented for post-signal diagnosis to identify the root cause of an OC event.

Based on the number of variables studied for each document (Fig. 9.l), two papers are classified as univariate and three as multivariate. One paper used a univariate control chart to monitor a multivariate process [26], achieved by monitoring the residuals of a prediction model. A summary of characteristics found in this category is presented in Table 7.

Regarding trend identification, it is not possible to establish a specific trend due to the low total count of current papers (five papers). However, it can be observed that cardiac surgery performance monitoring is the most frequent application [36], [64], [94], [109].

The limits and challenges that were spotted are the following:

- Data scarcity because the available datasets usually have few entries; data quality since the performance of the models in this category relies on correctly modeling the heterogeneity of subjects.
- Lack of homogeneity between surgeries and surgeons.

Lastly, the gaps for this category are the following:

- Similar to previous categories, normality is assumed for the monitored residuals with PCC but not tested, raising concerns about the accuracy of the reported performance of PCC.

TABLE 5. Biosurveillance documents overview.

General Application	Application	Chart	# Variables	Type	DD Method	DD Method Purpose	References
Incidence Rate Monitoring & Outbreak Detection	Influenza-like Illness Monitoring	Changepoint Detection Chart	Univariate	NCC	N/A	N/A	Parpoula, [97]
	COVID-19 Cases Monitoring in Iraq	Hotelling's T^2 & KNN Chart	Multivariate	DD Before & NCC	Kernel Principal Component Analysis (KPCA) & K-Nearest Neighbors (KNN)	Baseline Model Estimation	Fawzy & Ghalib, [18]
	Florida Influenza Incidence Rates Monitoring	EWMA	Multivariate	DD Before	Local Linear Kernel Smoothing (LLKS)	Baseline Model Estimation	Qiu & Yang, [14]
		CUSUM	Multivariate	DD Before	Kernel Smoothing (KS)	Baseline Model Estimation	Yang & Qiu, [19]
	Stroke Cases Monitoring	Hotelling's T^2 & Q Chart	Multivariate	DD Before	Backward Stepwise Logistic Regression (GAM)	Variable Selection & Baseline Model Estimation	Erfanian et al. [41]
	Japanese Influenza Monitoring	MEWMA	Multivariate	NCC	N/A	N/A	Liu et al. [62]
	Polio Cases Count Monitoring	CUSUM	Univariate	NCC	N/A	N/A	Wang & Qiu, [98]
	Hand, Foot and Mouth Disease Outbreaks Monitoring	CUSUM	Univariate	DD Before	Local Quadratic Kernel Smoothing (LQKS) & ARIMA Model	Baseline Model Estimation	Zhang J. et al. [60]
	Simulated Data	MCUSUM	Multivariate	NCC	N/A	N/A	Lee et al. [99]
	Rotavirus Outbreaks Monitoring	p Chart & CUSUM	Univariate	DD Before	Support Vector Machine (SVM)	Feature Extraction	Levin & Raman, [32]
Survival Analysis	Mortality Rate Monitoring	Hotelling's T^2 Chart	Multivariate	DD Before	Decision Tree	Response Prediction	Rakhmawan et al. [24]
	Lymphoma Patients Surviving Monitoring	Hotelling's T^2 & Deviation Charts	Multivariate	DD Before	Cox Proportional Hazards Model	Baseline Model Estimation	Xue et al. [68]
	AIDS Treatment Monitoring	Deviation Chart	Multivariate	DD Before	Support Vector Regressor (SVR)	Confidence Interval Computation & Baseline Model Estimation	Hung et al. [38]
Disease Occurrence Monitoring	Breast Cancer Monitoring	Wilcoxon Rank Sum + Mood Statistic Shewhart Chart	Multivariate	NCC	N/A	N/A	Yue & Liu, [100]
		MEWMA	Multivariate	NCC	N/A	N/A	Yue et al. [61]

TABLE 6. Hospital Management documents overview.

Application	Chart	# Variables	Type	DD Method	DD Method Purpose	References
Hospital's Electrical Consumption Monitoring	CUSUM	Multivariate	DD Before	Multiple Linear Regression (MLR)	Baseline Model Estimation	Zini & Carcasci, [101]
Drug Intravenous Infusion Monitoring	Moving Range Chart	Univariate	NCC	N/A	N/A	Obuseh et al. [102]
Patients' Attendance at ER	Generalized Likelihood Ratio (GLR) Chart	Univariate	NCC	N/A	N/A	Harrou et al. [103]
Hand Hygiene Monitoring	p Chart	Multivariate	DD Before	Locally Estimated Scatterplot Smoothing (LOESS)	Baseline Model Estimation	Wiemken et al. [63]
Health Information Technology Systems Monitoring	c Chart	Univariate	DD After	Discrete-Time Markov Chains (DTMC)	Post-Signal Diagnosis	Omitaomu et al. [104]
Air Quality Monitoring	S Chart	Univariate	DD Before	Multilayer Neural Network (MLP)	Response Prediction	Thomas et al. [23]
Medical Expenses Monitoring	X Chart	Univariate	DD After	Decision Tree	Post-Signal Diagnosis	Wu et al. [105]
Biomedical Databases Monitoring	Beta Distribution Chart	Both	DD Before	Kernel Density Estimation (KDE)	Baseline Model Estimation	Sáez et al. [106]
Global Standardized Mortality Ratios Monitoring	X Chart	Multivariate	DD Before	Decision Tree	Response Prediction	Minne et al. [25]
Bioassay Performance Monitoring based on Personnel Proficiency	Shewhart-Precedence Statistic	Univariate	NCC	N/A	N/A	Hothorn et al. [107]
Medication Errors Monitoring	Tukey's Chart	Univariate	NCC	N/A	N/A	Borckardt et al. [108]

- The lack of comparison with other proposals limits the ability to assess whether the proposed monitoring schemes outperform similar methods already published.

F. BIOASSAY MONITORING

Two documents are classified under this category. Both of them incorporate DD-before techniques, one using a PCC and the other an NCC. The purpose of all DD methods is to estimate the baseline model, allowing the creation of a monitorable function or response, even under online conditions.

Furthermore, both documents deal with multivariate processes. A multivariate control chart is used in [65] and [66] to monitor the process after estimating the baseline. Due to the limited number of papers in this category, it is not possible to identify a specific trend. Nevertheless, more applications in this field could be monitored using the DD method to estimate the baseline, followed by a multivariate control chart. These results are summarized in Table 8.

The observed limits and challenges in this category are the following:

TABLE 7. Surgical Performance documents overview.

Application	Chart	# Variables	Type	DD Method	DD Method Purpose	References
Cardiac Surgery Performance Monitoring	Artificial Neural Network Chart with risk-adjusted CUSUM inputs	Multivariate	NCC	N/A	N/A	Yeganeh et al. [109]
	CUSUM	Univariate	DD Before	Varying Coefficient Logistic Regression	Baseline Model Estimation	Li J. et al. [94]
	ME-WMV	Multivariate	DD After	Artificial Neural Network Input Gain Measurement Approximation (ANNIGMA)	Post-Signal Diagnosis	Gunaratne et al. [36]
	EWMA	Univariate	DD Before	Generalized Linear Model (GLM) based on Exponential Family Distributions	Baseline Model Estimation	Grigg & Spiegelhalter, [64]
Spinal Cord Monitoring during Surgery	X Chart	Multivariate	DD Before	Multi-Support Vector Regression (MSVR) & Least Squares Support Vector Regression (LS-SVR)	Response Prediction	Fan et al. [26]

TABLE 8. Bioassay Monitoring documents overview.

Application	Chart	# Variables	Type	DD Method	DD Method Purpose	References
Dose-Response Bioassay Performance Monitoring	Hotelling's T^2 Chart	Multivariate	DD Before	Integral Approximation with Generalized Least Squares + P-Spline Estimation	Baseline Model Estimation	Gomaa & Birch, [65]
Nanoparticles' Growth Monitoring	Multivariate Bayes-based Chart	Multivariate	DD Before & NCC	Geometric Time Series adjusted with Gibbs Sampling	Baseline Model Estimation	Park & Shrivastava, [66]

TABLE 9. Medical Equipment Monitoring documents overview.

Application	Chart	# Variables	Type	DD Method	DD Method Purpose	References
Alarm System Monitoring in Ventilators	p Chart	Univariate	DD Before	Defects Map (DM) using Agglomerative Hierarchical Clustering (AHC)	Feature Extraction	Novakovic & Marshall, [31]

- The correct modeling of time-series behavior is due to the complex characteristics of the data, such as stationarity, outliers, and temporal autocorrelation.
- Time-series alignment regarding the unequal observation times between samples violates the assumptions made by the control charts.

Ultimately, the gaps for this category are the same as the ones in the surgical performance category:

- The normally distributed residuals assumption is not tested.
- There is no comparison with other proposals.

G. MEDICAL EQUIPMENT MONITORING

Only one document [31], summarized in Table 9, monitors a univariate process with a DD-before approach combined with a PCC, where the DD method is employed for feature extraction. In this approach, the variable monitored was the proportion of false alarms presented by a ventilator with a p-chart.

Precisely for [31], the perceived limits and challenges are:

- The proposed method is unsuitable for online monitoring due to the variability of scenarios and a lack of generality.
- An extra sensor system is required to assess the status of an alarm, whether genuine or false.

The gaps for this paper are the following:

- The distribution assumption is not tested; thus, monitoring with NCC or DD-based charts that avoid this assumption could be explored.
- The implementation of data decorrelation techniques could improve the performance of the proposed method.
- The comparison of this proposal with other methods is lacking; hence, the proposal could be outperformed by others already published for similar processes.

Finally, even though there is only one paper in this category, it is important to include it as it represents a significant area in the healthcare field where researchers and experts can propose more applications and approaches.

H. CLASSIFICATION SUMMARY

The present summary primarily focuses on the impact of incorporating a DD method into the monitoring process. As shown in Fig. 1, it is evident that the most common approach is to include a DD method, whether before or after the chart, whereas the use of an NCC alone is still an emerging area in healthcare. Thus, NCC approaches are not considered in this summary, and future work using these charts is suggested.

In Table 10, three aspects are described for each category: 1) main advantages, 2) limits and challenges, and 3) gaps. These aspects are obtained from the inherent characteristics of each category application and the purpose for which a DD method is applied.

"Main advantages" show how a DD method enables the monitoring of a process or how the DD method improves it. "Limits & challenges" describe how capable approaches are and to what extent they can manage the nature of the data, and "gaps" present some aspects that ought to be considered to demonstrate the correct functioning of the proposed approach.

Moreover, by comparing Table 10 with the summary of previous reviews on the topic in Table 1, it can be noticed the positive impact on healthcare monitoring that the use of DD methods combined with a control chart has. This impact

TABLE 10. A summary table of DD methods combined with SPM charts for healthcare applications.

Category	Main Advantages	Limits & Challenges	Gaps
Patient Monitoring	• Baseline estimation and response prediction of the processes. • Accommodate complex data characteristics (e.g., heterogeneity of subjects, dynamic IC distributions, temporal autocorrelation, censored data, unequal observation times) • Feature extraction from complex bio signals (e.g., ECG & EEG).	• Data scarcity and data quality. • Correct modeling of time-series behavior (i.e., dynamic IC distributions and temporal autocorrelation). • Not general for every disease or patient with different phenotypic and genotypic backgrounds.	• The normality of residuals is not tested. • No observation time alignment in the time series. • No comparisons with other DD-based proposals.
Pharmacology Monitoring	• Baseline Estimation and Response Prediction of the processes. • Allows batch-to-batch analysis of industrial pharmacology processes.	• Curse of high dimensionality both in n and m. • Correct modeling of time series behavior (stationarity, outliers, temporal autocorrelation). • Finite horizon modeling instead of considering infinite production.	• Distribution assumptions are not tested. • No comparisons with other proposals. • Weak control limits (i.e., typical ±3 SD). • No data decorrelation. • Dimensionality reduction strategies ignore the clinical relevance of variables. • Finite horizon modeling.
Biosurveillance	• Baseline process estimation. • Accommodate complex data characteristics (e.g., temporal & spatial autocorrelation, censored data)	• Approaches are disease specific, and might be geography specific. • Correlation analysis is difficult when no other clinically relevant variables or biomarkers are included. • In some, correct modeling of time-series regarding stationarity.	• Although robust, memory-based PCC may fail. • No comparisons with other proposals. • In some, no optimization of hyperparameters is given.
Hospital Management	• Baseline Estimation and Response Prediction of the processes. • Post-signal diagnosis of OC events.	• Curse of high dimensionality both in n and m. • Misspecification of hyperparameters. • Correct modeling of time-series behavior (stationarity, outliers, temporal autocorrelation).	• The normally distributed residuals assumption is not tested. • Other distribution assumptions were not tested. • No data decorrelation. • No comparisons with other proposals. • No optimization of hyperparameters.
Surgical Performance	• Baseline estimation and response prediction by developing risk-adjusted control charts. • Consideration of subjects' heterogeneity. • Consideration of dynamic IC distributions.	• Data scarcity and data quality. • Not general for every surgeon or surgery.	• No comparisons with other proposals. • Normally distributed residuals assumption not tested.
Bioassay Monitoring	• Baseline Estimation via semiparametric and nonparametric DD methods. • Allows online monitoring of the process.	• Correct modeling of time-series behavior (stationarity, outliers, temporal autocorrelation). • Time series alignment.	• The normally distributed residuals assumption is not tested. • No comparisons with other proposals.
Medical Equipment Monitoring	• Feature extraction: Abnormal patterns representing false alarms in medical equipment.	• Not suitable for online monitoring in variable situations. • Need for an extra sensor system to assess the status of an alarm (genuine or false).	• Distribution assumption not tested. • No data decorrelation. • No comparisons with other proposals.

can be observed through various healthcare applications that have been made monitorable, as well as in the monitoring of multivariate processes.

VI. DISCUSSION OF RESULTS: HEALTHCARE OVERVIEW

According to our findings in this review, traditional PCC and NCC are limited when dealing with a large number of unstructured flows or random variables. The modeling capabilities of DD methods greatly assist the sequential analysis of a monitoring technique before or after the monitoring. When applied before, a structure is created into a statistic or profile to be assessed. When applied after the monitoring, a root cause analysis facilitates a post-signal diagnosis not limited to the in-control structure of monitored variables (see Section IV for a further explanation of DD methods' purposes). Additionally, as demonstrated in a significant number of proposals, PCC and NCC charts can be used to address scores generated by DD methods. The sequential analysis scheme provided by PCC and NCC boosts the sensitivity of scores, metrics, and responses obtained by DD methods.

As reinforced in this section, these techniques complement each other positively. However, not only advantages are summarized (see Section VI-A), but limits & challenges (see Section VI-B), and gaps (see Section VI-C) identified in the literature are also discussed, which should be considered for future research and practical applications in healthcare.

As mentioned earlier, the monitoring with NCC alone is not extensively discussed due to a lack of information to establish trends among the retrieved papers on the grounds of being an emerging area for healthcare applications. Additionally, it is worth mentioning that this review is delimited by the trends appearing in healthcare literature. We acknowledge that there are other trends involving DD and nonparametric approaches in SPM (e.g., zero-inflated methods, fuzzy logic methods, neutrosophic methods, and repetitive sampling methods, among others). However, not all of these trends are discussed in this review as they have not been part of the healthcare literature.

A. ADVANTAGES OF USING DATA-DRIVEN METHODS COMBINED WITH A CONTROL CHART

The introduction of DD methods into the SPM field has enabled the monitoring of new and more complex processes in healthcare. This advancement has been made possible due to the following advantages:

Design and develop novel control charts, such as k-charts, derived from *support vector data description* (SVDD), and deviation charts, using kernel-based methods (e.g., SVM, NN, KDE, clustering algorithms, one-class classifiers, among others) for their formulation [67].

Recognition of abnormal patterns in the data that are hidden or unknown to the human eye expert using kernel-based methods, specially NN and SVM, among others [67].

Adequate **modeling of highly autocorrelated datasets** using kernel-based methods, NN, and SVM, among others, to decrease the false alarm rate of the control chart [67].

The ability to **perform forecasts and build monitorable residuals** of data with unknown distributions using NN or PLS [46], [54], [67]; or with special characteristics, such as autocorrelated data with NN and SVM [67], or survival and censored data with the Cox proportional hazards model [44], [68].

Extraction and construction of trackable variables coming from complex data structures, such as a biosignal (e.g., ECG or EEG), applying PCA, independent component analysis (ICA), or wavelet transformation combined with NN or SVM methods [22], [33], [34], [48].

Selection of a subgroup of variables capable of capturing most of the variability of the process to deal with the curse of high dimensionality using NN, PLS, and decision trees or their ensembles [40], [46], [67].

Formulation of explainable models to gain insight into the process behavior by applying decision trees or their ensembles [40], [67] for **post-signal diagnosis**, outperforming traditional decomposition methods [35], [69] that establish the participation of each variable in the statistic plotted outside the control limits.

B. CHALLENGES & LIMITATIONS OF USING DATA-DRIVEN METHODS COMBINED WITH A CONTROL CHART

DD methods grant advantages to the monitoring process but also present limitations and challenges where work and research are still needed. Some of these are listed below:

Non-stationary processes: It is important to assess the stationarity of the process to model it correctly; otherwise, the abnormal patterns of the non-stationary component of the process could be missed, and the rate of false alarms in the resulting chart could be larger than expected [67], [70]. Healthcare examples are in disease outbreak detection studies [14], [19], where the disease has a seasonal component and where the IC distributions of the biomarkers in longitudinal studies of patients change through time [44], [71]. By this point, a proposal on how to model and manage the non-stationary component of the process prior to and during the monitoring is still needed. Another challenge, which is especially important when performing a post-signal diagnosis, is the change in the stationarity of the process when it becomes OC. In other words, the process can transit from a stationary behavior when it is IC to a non-stationary one when it is OC, meaning that the assumptions for the IC distribution no longer hold for the OC events. This is especially relevant when addressing a post-signal diagnosis.

High-reliability processes: A limitation arises when datasets do not have enough OC data to train most DD methods offline [67], [70]. There are some proposed strategies, such as one-class classifiers [73], [74], or artificial contrasts [75], but more work is needed.

High-dimensional processes: DD methods can perform feature selection for dimensionality reduction; however, certain questions about this feature selection still need to be answered [67], [76]. For example, what features are appropriate for a big data monitoring problem considering the data structure (e.g., continuous, discrete, or categorical)? What is the acceptable number of variables needed to avoid overfitting or considerable loss of information?

Optimization or misspecification of hyperparameters: A surprising issue encountered in DD-based control chart proposals is that, in many cases, a hyperparameter optimization step is not provided, and there is no evidence of the existence of this step at all [67]. It is common to see ''the popular'' hyperparameters used for the DD methods in the literature, leading to a misspecification problem where the results might be misleading.

Unequally spaced observation times: Control charts are intended to monitor equally spaced observation times. However, a common feature of healthcare data, particularly in longitudinal studies, is patient inconsistency in attending follow-up appointments on time. Therefore, modifications to these charts are needed to accommodate the observations adequately. Examples are given with an EWMA chart in

You & Qiu [44], and a DEWMA chart in Ashraf et al [71], along with the suggestion of not using ARL (Average Run Length) metrics to measure chart performance for unequally spaced observations, and instead use other metrics such as the average time to signal (ATS) [44], [47], [72]. Nevertheless, modifications for other SPM charts have not been proposed.

Data quality and scarcity: One main difference between industrial processes and healthcare applications is the quantity of available data. Typically, data acquisition involves high costs, time, and effort in healthcare applications, resulting in poor-quality data that does not accurately represent the process or is insufficient to train a DD method adequately [6]. Moreover, there are several real-world problems where the occurrence of a disease is so rare, such as the ones listed in the NORD Rare Disease Database,[1] that modeling it with a DD method could not be done [76].

Monitoring image data: It is still a big challenge due to the high correlation between the variables and the high dimensionality of the process [67]. Usually, these problems involve millions of variables (i.e., one variable per pixel), whereas multivariate control charts can deal with up to a dozen [42]. Therefore, there is still a chance to develop creative and intelligent approaches using SPM for healthcare applications in the imaging field (e.g., MRIs, X-rays, and CT scans), such as the design of charts capable of monitoring big data.

C. GAPS IN USING DATA-DRIVEN METHODS COMBINED WITH A CONTROL CHART

Whether in an industrial or healthcare context, a mistake remains a mistake. However, while in the industry, an error could represent an economic loss, in healthcare, it could mean an impaired quality of life for a patient or several deaths, depending on the specific application. For that reason, it is crucial to be aware of the current gaps that DD methods present in the monitoring of healthcare processes, which are presented below:

Improper control chart selection and design. A relevant aspect that must be considered for the monitoring of any process is the selection of a certain control chart and its characteristics, such as the size of the subgroups, the desired control limits based on a performance metric (commonly the desired ARL value), and the size of the shift to be detected [1], [4]. It is important to know the process components and behavior to be monitored to select the best control chart or a set of control charts to compare with. Also, it is important to identify deceiving trends in certain types of control charts recalled in the SPM literature [77], [78], [79], [80], [81] to avoid their use. If these recommendations are not followed, the number of false alarms or undetected signals could increase significantly. This issue is crucial when even an undetected OC event could mean the death of a patient in a patient monitoring case or the death of several people in a biosurveillance context.

[1] https://rarediseases.org/rare-diseases/

Deletion of missing data in a monitoring scheme. Another challenging task is collecting all the desired measurements (i.e., variables) from the patients, leading to the issue of missing data. Whether a patient lost an appointment, a nurse or physician performed a test incorrectly, or the physician did not recommend a certain test, it could lead to faulty readings and missing data [82]. One common practice in machine learning and statistical communities is to disregard these subjects [82]. Still, this could be a difficult, if not impossible, task for the medical community due to the usual small size of healthcare databases. In addition, healthcare data, especially data from patients' physical conditions, has heterogeneity characteristics [83] that several industrial processes lack. Every patient is unique, and despite presenting distinct measurements for a specific variable, they can be healthy (or IC) depending on the context of the patient and the studied problem, which means omitting a patient due to missing data may result in information loss, whereas imputing data may mask an OC event. Common advice is to estimate the missing data and declare the assumptions made with the data. Nevertheless, this question remains unanswered: ''What is the correct way to proceed with missing data?''

Dimensionality reduction, specifically in the Patient Monitoring case. A common practice in dealing with high-dimensional processes is to apply a dimensionality reduction technique. In this case, the major concern lies when the user is also interested in detecting OC events and knowing why. For instance, suppose it is only about discerning between IC and OC events. Then, the only risk is to not select a variable with the potential to detect a certain OC event, which in theory, the probability of information loss is minimal. However, the rejection of a less important variable or a redundant one due to the level of correlation with another selected variable [76] could lead to the ignoring of an organ or a complete system that is also damaged and relevant to the patient's condition. Another concern is miscommunication and poor collaboration between the medical and statistical fields. For instance, whether it is of interest why an OC event occurs or not, it is evident when the strategy to select variables relies only on the reduction strategy techniques. Their clinical relevance is ignored, meaning that the expert's opinion (i.e., healthcare professionals) is neglected, which could lead to a partial solution that, in the end, is still not enough to assist a healthcare professional in solving the real health problem.

Misspecification and performance comparison of DD-based control charts. Misspecification and comparison of the DD-based control chart proposal with other DD-based control charts is another point of miscommunication between the statistical community and the machine learning community when assessing the performance of their proposals, specifically when a combination of a DD method and a control chart is introduced. An important step in proposing a new approach is evaluating different scenarios to challenge it. Usually, the statistical community challenges its control charts by studying several scenarios that could be present (e.g., different numerical examples, shift sizes, and subgroup

sizes). Still, they do not report how are they challenging the DD methods they include in their proposals. For instance, a common practice in the machine learning community, analogous to the control chart challenge, is the optimization of the hyperparameters of the proposed DD method and comparing its DD method to others. However, in several retrieved articles in this review, the hyperparameters used were the ''popular'' ones. There were no comparisons between their DD-based control charts with other DD-based control chart proposals, but only with control charts alone. Therefore, the resulting model could be misspecified, resulting in non-optimal implementations.

Data assumptions. Other aspects to be concerned with are relying on data assumptions, for instance: 1) Independent observations with no autocorrelation [40], [67]; 2) Independent and identically distributed data (i.i.d.) [40]; 3) Equally spaced observations [44]; 4) Time series modeling based on the ARIMA or its variant assumptions [110]; 5) Quality of the data, meaning the representativeness of the process with the available data [6]; and 6) Leap of faith on the usual DD method hyperparameters [67].

VII. CONCLUSION

Statistical process monitoring charts have been implemented for various applications in different areas of healthcare. Beyond what has been described in recent review papers, it is possible to find different approaches where control charts are either parametric or nonparametric, or combined with a DD method before or after the monitoring process. According to the scientometric analysis, although the number of proposals is still limited, there is an increasing trend indicated by the growth kinetics, which instills positive growth expectations for the coming years.

Nonparametric charts prevent distribution assumptions, lowering the risk of information loss or misleading results due to an inadequate probability distribution. Data-driven methods have proven helpful for monitoring healthcare applications with unknown distributions and complex characteristics that control charts alone cannot handle. As a result, the application of statistical monitoring schemes has been expanded. In a nutshell, data-driven control charts and nonparametric charts are promising approaches researchers can use to monitor healthcare applications. However, there are still concerns and gaps produced by data-driven methods due to their limitations and the challenges that healthcare data bring to the table. Thus, there is plenty room for new proposals in this promising research area, which can aim to improve the performance of existing approaches, enhance our understanding, and broaden the scope of practical applications.

A. SUGGESTED FUTURE WORK

Based on the suggestions from recent papers and our own experience, we present a list of ideas and guidelines that might lead to future work in this collaboration between DD approaches and SPM methods in healthcare.

Design protocols on how to handle and monitor healthcare data: Healthcare data has several characteristics that differ from those in the industry. Thus, it is necessary to design protocols and guidelines on how to proceed and handle healthcare data. These protocols should provide guidance on various aspects, such as addressing data assumptions (e.g., the i.i.d. assumption), handling non-stationary components, selecting appropriate control charts, addressing misspecification of DD-methods' hyperparameters, and dealing with missing entries in healthcare data, among other considerations. By establishing such protocols, researchers can establish a baseline for studying and addressing these specific characteristics in healthcare data.

Use of explainable DD methods for post-signal diagnosis purposes: In some applications, such as high-reliability processes, detecting OC events and locating the culprits of a signal is critical. Explainable DD methods or DD-after approaches, such as decision trees and their ensembles, can enhance the understanding of cutoff values and provide improved diagnoses, particularly in the context of patient monitoring.

New DD-based control charts to deal with big data: A call for control charts capable of handling the trend of big data has been made. So far, current proposals have focused on applying variable selection techniques or summarizing the variables into their principal components, disregarding other variables with possible clinical relevance. To address this gap, new control chart proposals, either standalone or combined with DD methods, are required. These proposals could expand the range of healthcare applications to include those involving big data, such as imaging data and pharmacology monitoring processes. Furthermore, they could enhance existing applications by incorporating additional variables with clinical relevance.

Develop more models to evaluate the performance of the proposed DD-based control charts: To thoroughly evaluate the performance of proposed DD-based control charts, it is essential to develop robust models that assess their data assumptions and determine the optimal configuration of DD method hyperparameters. In addition to comparing the proposed DD-based charts with similar approaches, these models should cover a wide range of scenarios that may be encountered in future data. Simulations can be used to test the charts under various conditions. For example, You & Qiu [44], tested their proposed method using three different longitudinal setups in the context of patient monitoring. These setups considered within-subject data correlation, temporal path randomness, and non-Gaussian distributions using a combination of Gamma, Poisson, and standard normal probability distributions. While this example can serve as a standard for patient monitoring applications, it is important to address other healthcare fields that have not received adequate attention.

Modify SPM charts' design to deal with unequally spaced observation times: As highlighted in [44] and [71], current designs of SPM charts are not adequate to

monitor unequally spaced observations. Although modifications have been proposed for the design of EWMA [44] and DEWMA [71] charts, adjustments for other SPM charts are still lacking.

Avoid distribution assumptions by using NCC: As shown in Fig. 1 and 2, the increased popularity of combining DD methods with PCC for monitoring healthcare applications is evident. However, this approach still relies on distribution assumptions. In contrast, combining DD methods with an NCC is rare. Then, to facilitate the use of a solution in practical scenarios, new proposals could exploit the combination of the latter and explore if it can improve monitoring accuracy.

Collect new databases: Due to ethical conflicts, costs, and time, one difficult and vital task in developing a healthcare method is the collection of new databases. Adapting an approach designed for a particular application is not straightforward for other applications. To effectively test current approaches and develop new ones, it is necessary to gather a diverse range of databases encompassing various diseases, patients from different geographical locations, surgeries, and bioassays. Furthermore, it is essential to make these databases accessible to the entire research community, enabling collaboration and fostering advancements in healthcare monitoring.

Other ideas in healthcare include the following:

- Finite horizon proposals for drug production: Instead of assuming an infinite production line, exploring the use of finite horizon proposals for monitoring drug production in pharmacology could be beneficial. This is particularly relevant for production lines designed to work in a batch-to-batch fashion, where the process has a defined end.
- Online monitoring in biosurveillance processes: While the performance evaluation of biosurveillance models has been conducted using historical data of diseases or epidemics, there is a lack of demonstration with actual real-time online monitoring. Further research is needed to validate the effectiveness of biosurveillance models in real-time scenarios.
- Broadening the medical equipment monitoring area: There is a wide range of critical medical equipment items, such as vital signs monitors, hemodialysis machines, ECMOs, and anesthesia machines, that have not been addressed by SPM. This area presents significant potential for future research and development of monitoring approaches.

To further enhance the current review, we propose two additional topics for future work:

1) A comprehensive exploration of risk-adjusted control charts in healthcare to identify proposals that align with the search criteria of being data-driven. This analysis would delve into the application of risk-adjusted control charts within healthcare contexts, specifically focusing on their adherence to data-driven monitoring schemes.
2) The identification of appropriate performance measures for health data monitoring, based on the general classification of healthcare areas presented in this review, along with their specific applications. This investigation would involve determining suitable metrics and indicators to effectively evaluate the performance of health data monitoring in various healthcare domains.

VIII. SEARCH QUERIES

A. SEARCH QUERY FOR SCOPUS

Block 1: SPM & Control Charts Keywords

TITLE-ABS-KEY(((“Control Chart*” OR (“Statistical Process” PRE/0 (Control OR Monitor*))) OR (((*CUSUM AND Chart*) OR (“Cumulative Sum” PRE/1 Chart*) OR “*Parametric Cumulative Sum”) OR ((*EWMA* NOT (Newman* OR *Newmar*)) OR “Exponential* Weighted Moving Average”) OR Shewhart OR (*HWMA OR “Homogeneously Weighted Moving Average”) OR (*GWMA OR “General* Weighted Moving Average”) OR (MEC AND Chart*) OR ((“Progressive Mean” PRE/1 Chart*) OR (PM PRE/1 Chart*)) OR (Synthetic PRE/1 Chart*) OR ((Memory OR “Memory Type”) PRE/1 Chart*) OR (Mix* PRE/1 Chart*) OR (“Profile Monitor*” AND Chart*) OR (“General* Likelihood Ratio” PRE/1 Chart*) OR (Multivariate PRE/1 Chart*) OR (Adaptive PRE/1 Chart*) OR ((“Variable Sample Size” OR VSS) AND Chart*) OR ((“Variable Sampling Interval” OR VSI) AND Chart*) OR ((Changepoint OR “Change point”) AND (“Control Chart*” OR (Model AND Chart*))) OR ((“Sequential Probability Ratio Test” OR SPRT*) AND Chart*) OR (Robust PRE/1 Chart*) OR (Bootstrap PRE/1 Chart*) OR (PCA PRE/1 Chart*) OR (MD PRE/1 Chart*) OR ((“Mahalanobis* depth” OR “Mahalanobis* distance”) AND “Control Chart*”) OR ((“Runs Statistic” OR “Runs Test”) AND “Control Chart*”) OR (Tukey* PRE/1 Chart*) OR ((“Rank based” OR Rank) PRE/1 Chart*) OR (Sign PRE/1 Chart*) OR (“Signed Rank” PRE/1 Chart*) OR ((“Mann Whitney” PRE/1 Chart*) OR (“Mann Whitney Statistic” AND Chart*)) OR (Min PRE/1 Chart*) OR (Median PRE/1 Chart*) OR (“Mean Rank” PRE/1 Chart*) OR (“Scale Rank” PRE/1 Chart*) OR (kLINK PRE/1 Chart*) OR ((k PRE/1 Chart*) OR (Kernel AND “Control Chart*”))))

Block 2: Healthcare Keywords

AND ((Healthcare OR “Health Care” OR “Health Science”) OR “Public Health” OR “Private Health” OR (Bioassay* OR “Bio assay*”) OR (Heart OR Cardiac OR Cardio*) OR Blood* OR (Paedriatic* OR Pediatric*) OR COVID* OR Hormone* OR Endocrin* OR (Intestine* OR Entero*) OR Implant* OR Prosthetic* OR Tissue* OR Medic* OR Epidem* OR (Biosurveillance OR “Bio Surveillance”) OR Hospital* OR Clinic* OR Patient* OR Physician* OR (“Emergency Room” OR ER) OR (“Intensive Care Unit” OR ICU) OR Disease* OR Infectio* OR Illness* OR Patholog* OR “Syndromic Surveillance” OR Mortalit* OR Morbidit* OR Forensic* OR Imaging OR Radiolog* OR

(*Virus* NOT Antivirus) OR Bacter* OR Pancrea* OR Kidney* OR Pharma* OR Drug* OR Psych* OR Pandem* OR (Bone* NOT Backbone) OR Trauma* OR Skin OR Muscle* OR (Surger* OR Surgi*) OR (Liver* OR Hepato*) OR (Brain OR Neurol*) OR (Lung* OR Neumo*) OR (Cancer* OR Tumor* OR Carcinogenic) OR (Biomaterial* OR "Bio material*") OR (Gastro* OR Stomach) OR Immun* OR Therap* OR Biomedic*))

Block 3: Data-driven & Nonparametric Keywords

AND (("Data Driven" OR "Machine Learning" OR "Artificial Intelligence" OR "Decision Tree*" OR "Random Forest*" OR "Gradient Boosting" OR "Support Vector Machine" OR SVM OR "Neural Network*" OR "Nearest Neighbor" OR kNN OR "Deep Learning" OR "Partial Least Squares") OR (Nonparametric* OR "Non Parametric*" OR "Distribution Free" OR Semiparametric* OR "Semi Parametric*"))

B. SEARCH QUERY FOR WEB OF SCIENCE (WoS)

Block 1: SPM & Control Charts Keywords

TS = (((("Control Chart*" OR ("Statistical Process" NEAR/0 (Control OR Monitor*))) OR (((*CUSUM AND Chart*) OR ("Cumulative Sum" NEAR/1 Chart*) OR "*Parametric Cumulative Sum") OR ((*EWMA* NOT (Newman* OR *Newmar*)) OR "Exponential* Weighted Moving Average") OR Shewhart OR (*HWMA OR "Homogeneously Weighted Moving Average") OR (*GWMA OR "General* Weighted Moving Average") OR (MEC AND Chart*) OR (("Progressive Mean" NEAR/1 Chart*) OR (PM NEAR/1 Chart*)) OR (Synthetic NEAR/1 Chart*) OR ((Memory OR "Memory Type") NEAR/1 Chart*) OR (Mix* NEAR/1 Chart*) OR ("Profile Monitor*" AND Chart*) OR ("General* Likelihood Ratio" NEAR/1 Chart*) OR (Multivariate NEAR/1 Chart*) OR (Adaptive NEAR/1 Chart*) OR (("Variable Sample Size" OR VSS) AND Chart*) OR (("Variable Sampling Interval" OR VSI) AND Chart*) OR ((Changepoint OR "Change point") AND ("Control Chart*" OR (Model AND Chart*))) OR (("Sequential Probability Ratio Test" OR SPRT*) AND Chart*) OR (Robust NEAR/1 Chart*) OR (Bootstrap NEAR/1 Chart*) OR (PCA NEAR/1 Chart*) OR (MD NEAR/1 Chart*) OR (("Mahalanobis* depth" OR "Mahalanobis* distance") AND "Control Chart*") OR (("Runs Statistic" OR "Runs Test") AND "Control Chart*") OR (Tukey* NEAR/1 Chart*) OR (("Rank based" OR Rank) NEAR/1 Chart*) OR (Sign NEAR/1 Chart*) OR ("Signed Rank" NEAR/1 Chart*) OR (("Mann Whitney" NEAR/1 Chart*) OR ("Mann Whitney Statistic" AND Chart*)) OR (Min NEAR/1 Chart*) OR (Median NEAR/1 Chart*) OR ("Mean Rank" NEAR/1 Chart*) OR ("Scale Rank" NEAR/1 Chart*) OR (kLINK NEAR/1 Chart*) OR ((k NEAR/1 Chart*) OR (Kernel AND "Control Chart*"))))

Block 2: Healthcare Keywords

AND ((Healthcare OR "Health Care" OR "Health Science") OR "Public Health" OR "Private Health" OR (Bioassay* OR "Bio assay*") OR (Heart OR Cardiac OR Cardio*) OR Blood* OR (Paedriatic* OR Pediatric*) OR COVID* OR Hormone* OR Endocrin* OR (Intestine* OR Entero*) OR Implant* OR Prosthetic* OR Tissue* OR Medic* OR Epidem* OR (Biosurveillance OR "Bio Surveillance") OR Hospital* OR Clinic* OR Patient* OR Physician* OR ("Emergency Room" OR ER) OR ("Intensive Care Unit" OR ICU) OR Disease* OR Infectio* OR Illness* OR Patholog* OR "Syndromic Surveillance" OR Mortalit* OR Morbidit* OR Forensic* OR Imaging OR Radiolog* OR (*Virus* NOT Antivirus) OR Bacter* OR Pancrea* OR Kidney* OR Pharma* OR Drug* OR Psych* OR Pandem* OR (Bone* NOT Backbone) OR Trauma* OR Skin OR Muscle* OR (Surger* OR Surgi*) OR (Liver* OR Hepato*) OR (Brain OR Neurol*) OR (Lung* OR Neumo*) OR (Cancer* OR Tumor* OR Carcinogenic) OR (Biomaterial* OR "Bio material*") OR (Gastro* OR Stomach) OR Immun* OR Therap* OR Biomedic*))

Block 3: Data-driven & Nonparametric Keywords

AND (("Data Driven" OR "Machine Learning" OR "Artificial Intelligence" OR "Decision Tree*" OR "Random Forest*" OR "Gradient Boosting" OR "Support Vector Machine" OR SVM OR "Neural Network*" OR "Nearest Neighbor" OR kNN OR "Deep Learning" OR "Partial Least Squares") OR (Nonparametric* OR "Non Parametric*" OR "Distribution Free" OR Semiparametric* OR "Semi Parametric*"))

REFERENCES

[1] D. C. Montgomery, *Statistical Quality Control*, 7th ed. Hoboken, NJ, USA: Wiley, 2012.

[2] W. H. Woodall, B. M. Adams, and J. C. Benneyan, "The use of control charts in healthcare," in *Statistical Methods in Healthcare*. New York, NY, USA: Wiley, 2012, pp. 251–267.

[3] P. Qiu, "Big data? Statistical process control can help!" *Amer. Statistician*, vol. 74, no. 4, pp. 329–344, Oct. 2020, doi: 10.1080/00031305.2019.1700163.

[4] S. Chakraborti and M. A. Graham, *Nonparametric Statistical Process Control*, 1st ed. Hoboken, NJ, USA: Wiley, 2019.

[5] W. J. Conover, *Practical Nonparametric Statistics*, 3rd ed. New York, NY, USA: Wiley, 1999.

[6] V. Jordan and J. C. Benneyan, "Common challenges and pitfalls using SPC in healthcare," in *Statistical Methods in Healthcare*. New York, NY, USA: Wiley, 2012, pp. 268–285.

[7] G. Suman and D. Prajapati, "Control chart applications in healthcare: A literature review," *Int. J. Metrol. Quality Eng.*, vol. 9, pp. 1–21, Jan. 2018, doi: 10.1051/ijmqe/2018003.

[8] L. Slyngstad, "The contribution of variable control charts to quality improvement in healthcare: A literature review," *J. Healthc. Leadersh.*, vol. 13, pp. 221–230, Sep. 2021, doi: 10.2147/jhl.s319169.

[9] H. A. Wolfe, A. Taylor, and R. Subramanyam, "Statistics in quality improvement: Measurement and statistical process control," *Pediatric Anesthesia*, vol. 31, no. 5, pp. 539–547, May 2021, doi: 10.1111/pan.14163.

[10] J. D. Gibbons and S. Chakraborti, *Nonparametric Statistical Inference: Revised and Expanded*, 4th ed. Boca Raton, FL, USA: CRC Press, 2014.

[11] G. W. Corder and D. I. Foreman, *Nonparametric Statistics: A Step-by-Step Approach*, 2nd ed. Hoboken, NJ, USA: Wiley, 2014.

[12] P. Vinkler, "Scientometric indicators for the assessment of publications," in *The Evaluation of Research by Scientometric Indicators*. Oxford, U.K.: Elsevier, 2010, pp. 79–124.

[13] W. H. Woodall, "Bridging the gap between theory and practice in basic statistical process monitoring," *Qual. Eng.*, vol. 29, no. 1, pp. 2–15, 2017, doi: 10.1080/08982112.2016.1210449.

[14] P. Qiu and K. Yang, "Effective disease surveillance by using covariate information," *Statist. Med.*, vol. 40, no. 26, pp. 5725–5745, Nov. 2021, doi: 10.1002/sim.9150.

[15] W. Li, F. Zhao, J. Pan, and H. Qu, "Process monitoring and characterization for extraction of herbal medicines based on proton (1H) nuclear magnetic resonance spectroscopy and multivariate batch modeling: A case study," *J. Pharmaceutical Innov.*, vol. 18, no. 1, pp. 102–117, Mar. 2023, doi: 10.1007/s12247-022-09629-x.

[16] C. A. Duran-Villalobos, S. Goldrick, and B. Lennox, "Multivariate statistical process control of an industrial-scale fed-batch simulator," *Comput. Chem. Eng.*, vol. 132, pp. 1–13, Jan. 2020, doi: 10.1016/j.compchemeng.2019.106620.

[17] F. Tahir, M. T. Islam, J. Mack, J. Robertson, and D. Lovett, "Process monitoring and fault detection on a hot-melt extrusion process using in-line Raman spectroscopy and a hybrid soft sensor," *Comput. Chem. Eng.*, vol. 125, pp. 400–414, Jun. 2019, doi: 10.1016/j.compchemeng.2019.03.019.

[18] H. M. Fawzy and A. Ghalib, "Predicting of infected people with Corona virus (COVID-19) by using non-parametric quality control charts," *Int. J. Nonlinear Anal. Appl.*, vol. 13, pp. 2115–2126, Jan. 2022, doi: 10.22075/ijnaa.2022.5907.

[19] K. Yang and P. Qiu, "Online sequential monitoring of spatio-temporal disease incidence rates," *IISE Trans.*, vol. 52, no. 11, pp. 1218–1233, Nov. 2020, doi: 10.1080/24725854.2019.1696496.

[20] S. J. Khiabani, A. Batani, and E. Khanmohammadi, "A hybrid decision support system for heart failure diagnosis using neural networks and statistical process control," *Healthcare Anal.*, vol. 2, Nov. 2022, Art. no. 100110, doi: 10.1016/j.health.2022.100110.

[21] F. F. Jahantigh and A. Batani, "An engineering model for healthcare devices to control, detect, and diagnose medical errors," in *Proc. Int. Conf. Ind. Eng. Oper. Manage.*, Bandung, Indonesia, 2018, pp. 140–148.

[22] E. Leon, I. Montalban, S. Schlatter, and I. Dorronsoro, "Computer-mediated emotional regulation: Detection of emotional changes using non-parametric cumulative sum," in *Proc. Annu. Int. Conf. IEEE Eng. Med. Biol.*, Aug. 2010, pp. 1109–1112.

[23] P. Thomas, M. Suhner, and W. Derigent, "Relearning procedure to adapt pollutant prediction neural model: Choice of relearning algorithm," in *Proc. Int. Joint Conf. Neural Netw. (IJCNN)*, Jul. 2019, pp. 1–8.

[24] S. A. Rakhmawan, M. H. Omar, M. Riaz, and N. Abbas, "Hotelling t2 control chart for detecting changes in mortality models based on machine-learning decision tree," *Mathematics*, vol. 11, no. 3, p. 566, Jan. 2023, doi: 10.3390/math11030566.

[25] S. Eslami, N. de Keizer, E. de Jonge, S. E. de Rooij, A. Abu-Hanna, and L. Minne, "Statistical process control for monitoring standardized mortality ratios of a classification tree model," *Methods Inf. Med.*, vol. 51, no. 4, pp. 353–358, 2012, doi: 10.3414/me11-02-0044.

[26] B. Fan, H. Li, and Y. Hu, "An intelligent decision system for intraoperative somatosensory evoked potential monitoring," *IEEE Trans. Neural Syst. Rehabil. Eng.*, vol. 24, no. 2, pp. 300–307, Feb. 2016, doi: 10.1109/tnsre.2015.2477557.

[27] H.-M. Chi, H. Moskowitz, O. K. Ersoy, K. Altinkemer, P. F. Gavin, B. E. Huff, and B. A. Olsen, "Machine learning and genetic algorithms in pharmaceutical development and manufacturing processes," *Decis. Support Syst.*, vol. 48, no. 1, pp. 69–80, Dec. 2009, doi: 10.1016/j.dss.2009.06.010.

[28] I. Mandal, "Developing new machine learning ensembles for quality spine diagnosis," *Knowl.-Based Syst.*, vol. 73, pp. 298–310, Jan. 2015, doi: 10.1016/j.knosys.2014.10.012.

[29] M. Spooner and M. Kulahci, "Monitoring batch processes with dynamic time warping and k-nearest neighbours," *Chemometric Intell. Lab. Syst.*, vol. 183, pp. 102–112, Dec. 2018, doi: 10.1016/j.chemolab.2018.10.011.

[30] M. M. Hassan, S. Huda, J. Yearwood, H. F. Jelinek, and A. Almogren, "Multistage fusion approaches based on a generative model and multivariate exponentially weighted moving average for diagnosis of cardiovascular autonomic nerve dysfunction," *Inf. Fusion*, vol. 41, pp. 105–118, May 2018, doi: 10.1016/j.inffus.2017.08.004.

[31] A. Novakovic and A. H. Marshall, "Introducing the DM-P approach for analysing the performances of real-time clinical decision support systems," *Knowl. Based Syst.*, vol. 198, pp. 1–10, 2020, doi: 10.1016/j.knosys.2020.105877.

[32] J. E. Levin and S. Raman, "Early detection of rotavirus gastrointestinal illness outbreaks by multiple data sources and detection algorithms at a pediatric health system," in *Proc. AMIA Annu. Symp.*, 2005, pp. 445–449.

[33] M. Lang, "A low-complexity model-free approach for real-time cardiac anomaly detection based on singular spectrum analysis and nonparametric control charts," *Technologies*, vol. 6, no. 1, pp. 1–24, 2018, doi: 10.3390/technologies6010026.

[34] Y. Jung and H. Kim, "Detection of PVC by using a wavelet-based statistical ECG monitoring procedure," *Biomed. Signal Process. Control*, vol. 36, pp. 176–182, Jul. 2017, doi: 10.1016/j.bspc.2017.03.023.

[35] M. R. Pi na-Monarrez, "Generalization of the Hotelling's T^2 decomposition method to the R-chart," *Int. J. Ind. Eng.-Theory*, vol. 25, no. 2, pp. 200–211, 2018, doi: 10.23055/ijietap.2018.25.2.2053.

[36] N. G. T. Gunaratne, M. Abdollahian, and S. Huda, "Fault diagnostic of variance shifts in clinical monitoring using an artificial neural network input gain measurement approximation (ANNIGMA)," in *Information Technology New Generations*, S. Latifi, Ed. Vegas, NV, USA: Springer, 2018, pp. 295–300.

[37] A. Loggini, A. Mansour, F. El Ammar, C. Lazaridis, C. L. Kramer, Z. Bulwa, F. Saleh Velez, C. McCoy, and F. D. Goldenberg, "Early determinants of neurocritical care unit length of stay in patients with spontaneous intracerebral hemorrhage," *Neurocritical Care*, vol. 34, no. 2, pp. 485–491, Apr. 2021, doi: 10.1007/s12028-020-01046-7.

[38] Y.-C. Hung, W.-C. Tsai, S.-F. Yang, S.-C. Chuang, and Y.-K. Tseng, "Nonparametric profile monitoring in multi-dimensional data spaces," *J. Process Control*, vol. 22, no. 2, pp. 397–403, Feb. 2012, doi: 10.1016/j.jprocont.2011.12.009.

[39] T. M. Abuhay, Y. G. Nigatie, O. G. Metsker, and S. V. Kovalchuk, "Investigating application of change point analysis in monitoring health condition of acute coronary syndrome patients," *Proc. Comput. Sci.*, vol. 136, pp. 408–415, Jan. 2018.

[40] B. Efron and T. Hastie, *Computer Age Statistical Inference*, 1st ed. New York, NY, USA: Cambridge Univ. Press, 2016.

[41] M. Erfanian, B. S. Gildeh, and M. R. Azarpazhooh, "A new approach for monitoring healthcare performance using generalized additive profiles," *J. Stat. Comput. Simul.*, vol. 91, no. 1, pp. 167–179, Jan. 2021, doi: 10.1080/00949655.2020.1807981.

[42] F. Li, G. C. Runger, and E. Tuv, "Supervised learning for change-point detection," *Int. J. Prod. Res.*, vol. 44, no. 14, pp. 2853–2868, Jul. 2006, doi: 10.1080/00207540600669846.

[43] H. Raza, D. Rathee, S.-M. Zhou, H. Cecotti, and G. Prasad, "Covariate shift estimation based adaptive ensemble learning for handling non-stationarity in motor imagery related EEG-based brain-computer interface," *Neurocomputing*, vol. 343, pp. 154–166, May 2019, doi: 10.1016/j.neucom.2018.04.087.

[44] L. You and P. Qiu, "An effective method for online disease risk monitoring," *Technometrics*, vol. 62, no. 2, pp. 249–264, Apr. 2020, doi: 10.1080/00401706.2019.1625813.

[45] W. Li, W. Dou, X. Pu, and D. Xiang, "Monitoring individuals with irregular semiparametric longitudinal behaviour," *Qual. Technol. Quant. Manage.*, vol. 15, no. 1, pp. 37–52, Jan. 2018, doi: 10.1080/16843703.2017.1304045.

[46] M. Mansouri, M. N. Nounou, and H. N. Nounou, "Multiscale kernel PLS-based exponentially weighted-GLRT and its application to fault detection," *IEEE Trans. Emerg. Topics Comput. Intell.*, vol. 3, no. 1, pp. 49–58, Feb. 2019, doi: 10.1109/tetci.2017.2769111.

[47] J. Li and P. Qiu, "Nonparametric dynamic screening system for monitoring correlated longitudinal data," *IIE Trans.*, vol. 48, no. 8, pp. 772–786, Aug. 2016, doi: 10.1080/0740817x.2016.1146423.

[48] S. Chen, L. Chen, X. Zhang, and Z. Yang, "Screening of cardiac disease based on integrated modeling of heart rate variability," *Biomed. Signal Process Control*, vol. 63, pp. 1–10, Jan. 2021, doi: 10.1016/j.bspc.2020.102147.

[49] M. Mansouri, M. F. Harkat, S. Y. Teh, A. Al-khazraji, H. N. Nounou, and M. N. Nounou, "Model-based and data-driven with multiscale sum of squares double EWMA control chart for fault detection in biological systems," *J. Chemom.*, vol. 32, no. 12, pp. 1–16, 2018, doi: 10.1002/cem.3068.

[50] V. Hebbi, G. Thakur, and A. S. Rathore, "Process analytical technology application for protein PEGylation using near infrared spectroscopy: G-CSF as a case study," *J. Biotechnol.*, vol. 325, pp. 303–311, Jan. 2021, doi: 10.1016/j.jbiotec.2020.10.006.

[51] H. Xiong, X. Gong, and H. Qu, "Monitoring batch-to-batch reproducibility of liquid–liquid extraction process using in-line near-infrared spectroscopy combined with multivariate analysis," *J. Pharmaceutical Biomed. Anal.*, vol. 70, pp. 178–187, Nov. 2012, doi: 10.1016/j.jpba.2012.06.028.

[52] V. Lourenço, T. Herdling, G. Reich, J. C. Menezes, and D. Lochmann, "Combining microwave resonance technology to multivariate data analysis as a novel PAT tool to improve process understanding in fluid bed granulation," *Eur. J. Pharmaceutics Biopharmaceutics*, vol. 78, no. 3, pp. 513–521, Aug. 2011, doi: 10.1016/j.ejpb.2011.02.008.

[53] D. Colucci, J. M. Prats-Montalbán, A. Ferrer, and D. Fissore, "On-line product quality and process failure monitoring in freeze-drying of pharmaceutical products," *Drying Technol.*, vol. 39, no. 2, pp. 134–147, Jan. 2021, doi: 10.1080/07373937.2019.1614949.

[54] A. F. T. Silva, M. C. Sarraguça, P. R. Ribeiro, A. O. Santos, T. De Beer, and J. A. Lopes, "Statistical process control of cocrystallization processes: A comparison between OPLS and PLS," *Int. J. Pharmaceutics*, vol. 520, nos. 1–2, pp. 29–38, Mar. 2017, doi: 10.1016/j.ijpharm.2017.01.052.

[55] J. W. Rydzak, D. E. White, C. Y. Airiau, J. T. Sterbenz, B. D. York, D. J. Clancy, and Q. Dai, "Real-time process analytical technology assurance for flow synthesis of oligonucleotides," *Organic Process Res. Develop.*, vol. 19, no. 1, pp. 203–214, Jan. 2015, doi: 10.1021/op500035j.

[56] R. Kona, H. Qu, R. Mattes, B. Jancsik, R. M. Fahmy, and S. W. Hoag, "Application of in-line near infrared spectroscopy and multivariate batch modeling for process monitoring in fluid bed granulation," *Int. J. Pharmaceutics*, vol. 452, nos. 1–2, pp. 63–72, Aug. 2013, doi: 10.1016/j.ijpharm.2013.04.039.

[57] J. G. Rosas, M. Blanco, J. M. González, and M. Alcalá, "Quality by design approach of a pharmaceutical gel manufacturing process—Part 2: Near infrared monitoring of composition and physical parameters," *J. Pharmaceutical Sci.*, vol. 100, no. 10, pp. 4442–4451, Oct. 2011, doi: 10.1002/jps.22607.

[58] L. Schweitz, M. Fransson, L. Karlsson, A. Torstensson, and E. Johansson, "On-line process control of gradient elution liquid chromatography," *Anal. Chem.*, vol. 76, no. 16, pp. 4875–4880, Aug. 2004, doi: 10.1021/ac0497050.

[59] A. Burggraeve, T. Van Den Kerkhof, M. Hellings, J. P. Remon, C. Vervaet, and T. De Beer, "Batch statistical process control of a fluid bed granulation process using in-line spatial filter velocimetry and product temperature measurements," *Eur. J. Pharmaceutical Sci.*, vol. 42, no. 5, pp. 584–592, Apr. 2011, doi: 10.1016/j.ejps.2011.03.002.

[60] J. Zhang, Y. Kang, Y. Yang, and P. Qiu, "Statistical monitoring of the hand, foot and mouth disease in China," *Biometrics*, vol. 71, no. 3, pp. 841–850, Sep. 2015, doi: 10.1111/biom.12301.

[61] J. Yue, N. Zhao, and L. Liu, "Prediction and monitoring method for breast cancer: A case study for data from the University hospital centre of Coimbra," *Cancer Manage. Res.*, vol. 12, pp. 1887–1893, Mar. 2020, doi: 10.2147/cmar.s242027.

[62] L. Liu, J. Yue, X. Lai, J. Huang, and J. Zhang, "Multivariate nonparametric chart for influenza epidemic monitoring," *Sci. Rep.*, vol. 9, no. 1, pp. 1–11, Nov. 2019, doi: 10.1038/s41598-019-53908-6.

[63] T. L. Wiemken, L. Hainaut, H. Bodenschatz, and R. Varghese, "Hand hygiene compliance surveillance with time series anomaly detection," *Amer. J. Infection Control*, vol. 47, no. 12, pp. 1449–1452, Dec. 2019, doi: 10.1016/j.ajic.2019.06.003.

[64] O. Grigg and D. Spiegelhalter, "A simple risk-adjusted exponentially weighted moving average," *J. Amer. Stat. Assoc.*, vol. 102, no. 477, pp. 140–152, Mar. 2007, doi: 10.1198/016214506000001121.

[65] A. S. Gomaa and J. B. Birch, "A semiparametric nonlinear mixed model approach to phase I profile monitoring. *Commun. Stat. Simul. Comput.*, vol. 48, no. 6, pp. 1677–1693, 2019, doi: 10.1080/03610918.2017.1422751.

[66] C. Park and A. K. Shrivastava, "Multimode geometric-profile monitoring with correlated image data and its application to nanoparticle self-assembly processes," *J. Quality Technol.*, vol. 46, no. 3, pp. 216–233, Jul. 2014, doi: 10.1080/00224065.2014.11917966.

[67] P. H. Tran, A. Ahmadi Nadi, T. H. Nguyen, K. D. Tran, and K. P. Tran, "Application of machine learning in statistical process control charts: A survey and perspective," in *Control Charts and Machine Learning for Anomaly Detection in Manufacturing*, 1st ed. Cham, Switzerland: Springer, 2022, pp. 7–42.

[68] Y. Xue, J. Yan, and E. D. Schifano, "Simultaneous monitoring for regression coefficients and baseline hazard profile in cox modeling of time-to-event data," *Biostatistics*, vol. 22, no. 4, pp. 756–771, Oct. 2021, doi: 10.1093/biostatistics/kxz064.

[69] G. C. Runger, F. B. Alt, and D. C. Montgomery, "Contributors to a multivariate statistical process control chart signal," *Commun. Statist. Theory Methods*, vol. 25, no. 10, pp. 2203–2213, Jan. 1996, doi: 10.1080/03610929608831832.

[70] X. Xie and P. Qiu, "Machine learning control charts for monitoring serially correlated data," in *Control Charts and Machine Learning for Anomaly Detection in Manufacturing*, 1st ed. Cham, Switzerland: Springer, 2022, pp. 131–147.

[71] A. Ashraf, S. Ali, and I. Shah, "Online disease risk monitoring using DEWMA control chart," *Expert Syst. Appl.*, vol. 180, pp. 1–14, Oct. 2021, doi: 10.1016/j.eswa.2021.115059.

[72] J. Li and P. Qiu, "Construction of an efficient multivariate dynamic screening system," *Qual. Rel. Eng. Int.*, vol. 33, no. 8, pp. 1969–1981, Dec. 2017, doi: 10.1002/qre.2160.

[73] C. Désir, S. Bernard, C. Petitjean, and L. Heutte, "One class random forests," *Pattern Recognit.*, vol. 46, no. 12, pp. 3490–3506, Dec. 2013, doi: 10.1016/j.patcog.2013.05.022.

[74] F. T. Liu, K. M. Ting, and Z.-H. Zhou, "Isolation-based anomaly detection," *ACM Trans. Knowl. Discovery From Data*, vol. 6, no. 1, pp. 1–39, Mar. 2012, doi: 10.1145/2133360.2133363.

[75] K. S. Shin, I. S. Lee, and J. G. Baek, "An improved real-time contrasts control chart using novelty detection and variable importance," *Appl. Sci.*, vol. 9, no. 1, pp. 1–11, 2019, doi: 10.3390/app9010173.

[76] J. Li, K. Cheng, S. Wang, F. Morstatter, R. P. Trevino, J. Tang, and H. Liu, "Feature selection: A data perspective," *ACM Comput. Surv.*, vol. 50, no. 6, pp. 1–45, Nov. 2018, doi: 10.1145/3136625.

[77] S. Knoth, "An expanded case against synthetic-type control charts," *Qual. Rel. Eng. Int.*, vol. 38, no. 6, pp. 3197–3215, Oct. 2022, doi: 10.1002/qre.3128.

[78] S. Knoth, N. A. Saleh, M. A. Mahmoud, W. H. Woodall, and V. G. Tercero-Gómez, "A critique of a variety of 'memory-based' process monitoring methods," *J. Quality Technol.*, vol. 55, no. 1, pp. 1–27, 2022, doi: 10.1080/00224065.2022.2034487.

[79] S. Knoth, W. H. Woodall, and V. G. Tercero-Gómez, "The case against generally weighted moving average (GWMA) control charts," *Qual. Eng.*, vol. 34, no. 1, pp. 75–81, Jan. 2022, doi: 10.1080/08982112.2021.2002359.

[80] S. Knoth, V. G. Tercero-Gómez, M. Khakifirooz, and W. H. Woodall, "The impracticality of homogeneously weighted moving average and progressive mean control chart approaches," *Qual. Rel. Eng. Int.*, vol. 37, no. 8, pp. 3779–3794, Dec. 2021, doi: 10.1002/qre.2950.

[81] M. A. Mahmoud and W. H. Woodall, "An evaluation of the double exponentially weighted moving average control chart," *Commun. Statist. Simul. Comput.*, vol. 39, no. 5, pp. 933–949, Apr. 2010, doi: 10.1080/03610911003663907.

[82] S. H. Bots, K. R. Siegersma, N. C. Onland-Moret, F. W. Asselbergs, G. A. Somsen, I. I. Tulevski, H. M. den Ruijter, and L. Hofstra, "Routine clinical care data from thirteen cardiac outpatient clinics: Design of the cardiology centers of The Netherlands (CCN) database," *BMC Cardiovascular Disorders*, vol. 21, no. 1, pp. 1–9, Dec. 2021, doi: 10.1186/s12872-021-02020-7.

[83] I. D. Dinov, "Methodological challenges and analytic opportunities for modeling and interpreting big healthcare data," *GigaScience*, vol. 5, no. 1, pp. 1–15, Dec. 2016, doi: 10.1186/s13742-016-0117-6.

[84] C. A. Hughes Driscoll, N. L. Davis, M. Miles, and D. El-Metwally, "A quality improvement project to improve evidence-based inhaled nitric oxide use," *Respiratory Care*, vol. 63, no. 1, pp. 20–27, Jan. 2018, doi: 10.4187/RESPCARE.05619.

[85] I. Phinikettos and A. Gandy, "An omnibus CUSUM chart for monitoring time to event data," *Lifetime Data Anal.*, vol. 20, no. 3, pp. 481–494, Jul. 2014, doi: 10.1007/s10985-013-9281-5.

[86] K. Malinowski, T. M. Avoy, R. George, S. Dieterich, and W. D'Souza, "WE-D-204B-05: Online monitoring and error detection of real-time tumor displacement prediction accuracy using statistical process control," *Med. Phys.*, vol. 37, p. 3430, Jun. 2010, doi: 10.1118/1.3469402.

[87] K. Malinowski, T. McAvoy, R. George, S. Dieterich, and W. D'Souza, "TU-G-BRC-08: Maintaining tumor targeting accuracy in gating and tracking systems for respiration-induced tumor motion," *Med. Phys.*, vol. 38, p. 3782, Jun. 2011, doi: 10.1118/1.3613237.

[88] K. Malinowski, T. J. McAvoy, R. George, S. Dieterich, and W. D. D'Souza, "Online monitoring and error detection of real-time tumor displacement prediction accuracy using control limits on respiratory surrogate statistics," *Med. Phys.*, vol. 39, no. 4, pp. 2042–2048, Mar. 2012, doi: 10.1118/1.3676690.

[89] K. Malinowski, T. J. McAvoy, R. George, S. Dieterich, and W. D. D'Souza, "Maintaining tumor targeting accuracy in real-time motion compensation systems for respiration-induced tumor motion," *Med. Phys.*, vol. 40, no. 7, Jun. 2013, Art. no. 071709, doi: 10.1118/1.4808119.
[90] H. Yang, C. Kan, A. Krall, and D. Finke, "Network modeling and Internet of Things for smart and connected health systems—A case study for smart heart health monitoring and management," *IISE Trans. Healthcare Syst. Eng.*, vol. 10, no. 3, pp. 159–171, Jul. 2020, doi: 10.1080/24725579.2020.1741738.
[91] F. Lombard, D. M. Hawkins, and C. J. Potgieter, "Sequential rank CUSUM charts for angular data," *Comput. Statist. Data Anal.*, vol. 105, pp. 268–279, Jan. 2017, doi: 10.1016/j.csda.2016.08.001.
[92] F. Lombard, D. M. Hawkins, and C. J. Potgieter, "Nonparametric CUSUM charts for circular data with applications in health science and astrophysics," *Revstat Stat. J.*, vol. 18, no. 4, pp. 461–481, 2020.
[93] J. L. Vasko, L. Aume, S. Tamrakar, S. C. I. Colachis, C. F. Dunlap, A. Rich, E. C. Meyers, D. Gabrieli, and D. A. Friedenberg, "Increasing robustness of brain–computer interfaces through automatic detection and removal of corrupted input signals," *Frontiers Neurosci.*, vol. 16, p. 465, Apr. 2022, doi: 10.3389/fnins.2022.858377.
[94] J. Li, J. Jiang, X. Jiang, and L. Liu, "Risk-adjusted monitoring of surgical performance," *PLoS ONE*, vol. 13, no. 8, Aug. 2018, Art. no. e0200915, doi: 10.1371/journal.pone.0200915.
[95] A. A. Toor, M. Usman, F. Younas, M. Habib, and A. C. M. Fong, "Efficient mining of IoT based data streams for advanced computer vision systems," *Multimedia Tools. Appl.*, Jun. 2020, doi: 10.1007/s11042-020-09175-z.
[96] P. Muthudoss, S. Kumar, E. Y. C. Ann, K. J. Young, R. L. R. Chi, R. Allada, B. Jayagopal, A. Dubala, I. B. Babla, S. Das, S. Mhetre, I. Saraf, and A. Paudel, "Topologically directed confocal Raman imaging (TD-CRI): Advanced Raman imaging towards compositional and micromeritic profiling of a commercial tablet components," *J. Pharmaceutical Biomed. Anal.*, vol. 210, Feb. 2022, Art. no. 114581, doi: 10.1016/j.jpba.2022.114581.
[97] C. Parpoula, "A distribution-free control charting technique based on change-point analysis for detection of epidemics," *Stat. Methods Med. Res.*, vol. 31, no. 6, pp. 1067–1084, Jun. 2022, doi: 10.1177/09622802221079347.
[98] Z. Wang and P. Qiu, "Count data monitoring: Parametric or nonparametric?" *Qual. Rel. Eng. Int.*, vol. 34, no. 8, pp. 1763–1774, Dec. 2018, doi: 10.1002/qre.2368.
[99] M. L. Lee, D. Goldsman, and S.-H. Kim, "Robust distribution-free multivariate CUSUM charts for spatiotemporal biosurveillance in the presence of spatial correlation," *IIE Trans. Healthcare Syst. Eng.*, vol. 5, no. 2, pp. 74–88, Apr. 2015, doi: 10.1080/19488300.2015.1017674.
[100] J. Yue and L. Liu, "A new nonparametric multivariate control scheme for simultaneous monitoring changes in location and scale," *Comput. Math. Methods Med.*, vol. 2022, pp. 1–11, Jul. 2022, doi: 10.1155/2022/3385825.
[101] M. Zini and C. Carcasci, "Developing of an offline monitoring method for the energy demand of a healthcare facility in Italy," *J. Sustain. Develop. Energy, Water Environ. Syst.*, vol. 10, no. 4, pp. 1–22, Dec. 2022, doi: 10.13044/j.sdewes.d10.0421.
[102] M. Obuseh, D. Yu, and P. DeLaurentis, "Detecting unusual intravenous infusion alerting patterns with machine learning algorithms," *Biomed. Instrum. Technol.*, vol. 56, no. 2, pp. 58–70, Apr. 2022, doi: 10.2345/1943-5967-56.2.58.
[103] F. Harrou, F. Kadri, Y. Sun, and S. Khadraoui, "Monitoring patient flow in a hospital emergency department: ARMA-based nonparametric GLRT scheme," *Health Informat. J.*, vol. 27, no. 2, Apr. 2021, Art. no. 146045822110216, doi: 10.1177/14604582211021649.
[104] O. A. Omitaomu, O. Ozmen, M. M. Olama, L. L. Pullum, T. Kuruganti, J. Nutaro, H. B. Klasky, H. Zandi, A. Advani, A. L. Laurio, M. Ward, J. Scott, and J. R. Nebeker, "Real-time automated hazard detection framework for health information technology systems," *Health Syst.*, vol. 8, no. 3, pp. 190–202, Sep. 2019, doi: 10.1080/20476965.2019.1599701.
[105] T. S. Wu, Y. S. Liu, S. C. Chen, and C. H. Cheng, "The control technology of medical expenses: A combination of data mining and quality control chart," in *Proc. ICEPECA*, Wuhan, China, 2019, pp. 387–392.
[106] C. Sáez, P. P. Rodrigues, J. Gama, M. Robles, and J. M. García-Gómez, "Probabilistic change detection and visualization methods for the assessment of temporal stability in biomedical data quality," *Data Mining Knowl. Discovery*, vol. 29, no. 4, pp. 950–975, Jul. 2015, doi: 10.1007/s10618-014-0378-6.
[107] L. A. Hothorn, D. Gerhard, and M. Hofmann, "Parametric and non-parametric prediction intervals based phase II control charts for repeated bioassay data," *Biologicals*, vol. 37, no. 5, pp. 323–330, Oct. 2009, doi: 10.1016/j.biologicals.2009.07.001.
[108] J. J. Borckardt, C. Pelic, J. Herbert, D. Borckardt, M. R. Nash, H. Cooney, and S. Hardesty, "An autocorrelation-corrected nonparametric control chart technique for health care quality applications," *Qual. Manage. Health Care*, vol. 15, no. 3, pp. 157–162, Jul. 2006, doi: 10.1097/00019514-200607000-00005.
[109] A. Yeganeh, A. Shadman, S. C. Shongwe, and S. A. Abbasi, "Employing evolutionary artificial neural network in risk-adjusted monitoring of surgical performance," *Neural Comput. Appl.*, vol. 35, no. 14, pp. 10677–10693, May 2023, doi: 10.1007/s00521-023-08257-x.
[110] D. C. Montgomery, C. L. Jennings, and M. Kulahci. *Introduction to Time Series Analysis and Forecasting*, 2nd ed. Hoboken, NJ, USA: Wiley, 2015.

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