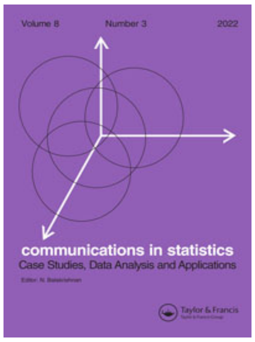

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Surveilling public health through statistical process monitoring: A literature review and a unified framework

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CASE REPORT

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Surveilling public health through statistical process monitoring: A literature review and a unified framework

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ABSTRACT
A challenge, in the era of economic crisis and uncertainty, is to provide health care services in an efficient and effective manner. The protection of public health, the provision of quality healthcare services to patients, the location of health centers, the geographical distribution of patients, and the provision of specialist services are some of the topics that the government and/or a health organization responsible for health care services provision has to arrange. Other topics are the assessment of quality, safety, and effectiveness of healthcare services provided by healthcare providers. Moreover, a central pylon in designing healthcare policy is expenditure monitoring and control. However, among all these topics the most significant is the protection of public health; especially now that viruses such as Coronavirus are spreading rapidly worldwide. This paper aims to review the use of Statistical Process Monitoring techniques in the public health domain in order to improve health care decision-making under uncertainty and further on to provide an innovative three-layer framework for the collection, processing, and real-time analysis of related data like Coronavirus or any other infectious disease that will emerge in the future for both proper and effective case management and effective health policy planning.

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Control Charts; decision making; healthcare provision; multivariate Statistical process monitoring; statistical process monitoring; stochastic modeling

1. Introduction

Healthcare is a notion with several definitions. For example, the Oxford dictionary defines healthcare as "the organized provision of medical care to individuals or a community" while according to the Cambridge dictionary, it is defined as "the set of services provided by a country or an organization for the treatment of the physically and the mentally ill." Healthcare is closely related to public health which is defined as "the science and art of preventing disease, prolonging life, and promoting health through the organized efforts and informed choices of society, organizations, public and private communities, and individuals" (Winslow 1920). A similar notion is biosurveillance or public health surveillance, which refers to the monitoring of a wide range of prediagnostic and diagnostic data for the purpose of enhancing mainly the ability of the public

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health infrastructure to detect, investigate, and respond to disease outbreaks. As a consequence, biosurveillance's main objective is to ensure public health.

There are two main challenges in healthcare services provision, as well as in the public health domain. The first one is to make accurate predictions for future needs through modeling historic data (Phase I: Modeling Phase) while the latter is to continuously monitor the provided healthcare services (Phase II: Prospective Monitoring). This intensifies the need for realistic, reliable models for monitoring healthcare processes. Uncertainty and variability are characteristic elements of healthcare systems and public health status. Therefore, to assist clinical decision making, facilitate location and planning, and evaluate treatments, in order to secure public health, stochastic models are required (Brailsford 2007). Stochastic models are more data-intensive than deterministic models but tend to provide a more realistic description of the system.

According to World Health Organization (WHO) data, on January 21, 2022, 340,543,962 cases and 5,570,163 deaths had been confirmed from COVID19. Given the seriousness of the virus and its consequences worldwide, it immediately emerges that there is a need to develop a dynamic system for the effective management of information on the coronavirus epidemic and any future outbreaks that will have a severe impact on the public health.

One of the first techniques used to monitor healthcare processes and public health was the Statistical Process Monitoring (SPM). Motivated by the fact that the most well-known tool of SPM is the control chart, Mohammed, Worthington, and Woodall (2008) published a tutorial for healthcare practitioners on plotting basic control charts. Whenever we have continuous data the $\bar{x}-$ and mr-charts are often suitable while for discrete data, the p-chart, u-chart and the c-chart are appropriate.

The application of SPM techniques in healthcare processes began in the late 1980s. Berwick (1989) discussed the necessity of continuous improvement in health care while Berwick (1991) discussed the case of controlling variation in healthcare using industrial quality management methods. An excellent review of the use of SPM in the field of public health was given by Woodall (2006) before approximately fifteen years while Tsui et al. (2008) in 2008 presented a review of several methods for healthcare, public health, and syndromic surveillance. The main SPM technique, i.e., control chart has been widely used to monitor patients' health, hospitals' performance, in public health surveillance, etc. Furthermore, SPM techniques have been used (see, e.g., Steiner, Cook, and Farewall 1999, 2000; Carey and Stake 2003; Sonesson and Bock 2003) for monitoring medical variables like incidences of infections, the number of deaths, waiting time from surgery to full recovery, waiting time in the emergency room, etc in hospital-level or single patients medical data for providing a quick diagnostic procedure, that may supplement and simultaneously enhance the usual medical practice. Unkel et al. (2012) devoted a section of their review paper on the statistical methods used for the prospective detection of infectious disease outbreaks to control charts. Woodall and Montgomery (2014) presented an overview of research and applications SPM, in a number of important areas, including health-related monitoring and spatiotemporal surveillance.

Since most of the practical problems are related to many dependent characteristics (variables), the use of Multivariate SPM (MSPM) techniques can be very efficient to the whole process of the health organization, aiming to control the proper functioning of each of them. In order to improve the quality of institutions, several researchers have built or simply used multivariate control charts. Recently, Bersimis, Sgora, and Psarakis (2018) gave a comprehensive review paper on the use of the MSPM in non-industrial processes, where a substantial part is related to the use of MSPM techniques in health. Specifically, they presented the application of MSPM techniques to health protection, health surveillance, monitoring health organizations, public health, safeguarding pharmaceutical, diagnostic and clinical safety, while they pointed out that MSPM techniques used in health should be able to deal with non-normality, discrete distributions, autocorrelation, individual observations, adaptiveness, and interpretation of an out-of-control signal.

As in all fields, so in healthcare processes, there are two major types of data: continuous (measurement) data and discrete (or count or attribute) data. Examples of continuous data in healthcare are weight, height, blood pressure, length of stay and time from referral to surgery. Examples of discrete data in healthcare are the number of admissions, the number of prescriptions, the number of errors, the number of patients waiting.

The aim of this paper is to thoroughly discuss the use of SPM and MSPM, and especially the use of control charts, in healthcare processes, on the basis of a three-layer framework for the collection, processing and real-time analysis of medical data, such as coronavirus-related data or any other infectious disease that will emerge in the future, for both proper and effective case management and effective health policy planning. The three layers of the framework are the patient layer (or generally the citizen layer), the health organization layer and finally the community layer. A similar categorization has been used in the review paper of Bersimis, Sgora, and Psarakis (2018).

The paper is organized as follows. In the second section, we present a comprehensive literature review of the use of SPM and MSPM for monitoring patient-related variables. In Section 3, we present a thorough literature review of the use of SPM and MSPM for monitoring health organization processes. In Section 4, we present a comprehensive literature review of the use of SPM and MSPM for monitoring public health. In Section 5, we describe an innovative framework for public health surveillance, which is based on SPM and which is built as a pyramid having as a base the continuous individual's health monitoring, the health organizations monitoring as an intermediate layer, and finally at the top the public health monitoring. In the sixth section, an indicative simulated example of the framework's operation is given. Finally, we close the paper with some concluding remarks in Section 7.

2. SPM applied in the citizen layer

The surveillance/monitoring of single patients (or healthy individuals) has been introduced as a quick diagnostic tool that may supplement and simultaneously enhance the usual medical practice. For example, one might monitor the blood volume of a patient and quickly recognize a possible decrease which is due to a tumor. Furthermore, once a biochemical marker is regulated, during the treatment, the objective is to ensure that measurements remain within some reasonable limits. Thus it is necessary to continuously monitor the biochemical measurements. Several authors have dealt with the monitoring of patients' characteristics using univariate and/or multivariate SPM techniques. In the context of prevention, we can also monitor healthy individuals with the aim of early detection of a possible illness.

2.1. The use of SPM

Boggs et al. (1999) had explored the role of control charts in the continuous monitoring of lung function of patients with asthma at home. In asthma, control charts besides providing a better understanding of the functional capability of the asthma care system that patients are following, they also give a patient-specific, statistical signals of change (Boggs 2005). The control charts are also capable of assessing asymptomatic patients for a change in function, predicting severe asthma attacks and evaluating new environmental and non-environmental triggers for a change in function (Boggs 2005). Also, in the context of chronic diseases, Glasziou, Irwig, and Mant (2005) suggested the use of control charts during treatment to identify possible deviations from the normal values. This can help the process of registering and deciding treatment changes.

Alemi and Neuhauser (2004) discussed the use of time-between control charts, which are based on the assumption of recurrent events in repeated trials, for monitoring asthma attacks. The time-between control charts are especially suited for monitoring rare events. Bucuvalas et al. (2005) applied SPM techniques to manage calcineurin inhibitor (CNI) blood levels, under the hypothesis that the use of SPM would increase the proportion of CNI blood levels in the target range. The researchers used control charts to identify excessive variation, through CNI blood levels that exceed 2 standard deviations from the mean, through three consecutive CNI blood levels exceeding 1 standard deviation from the mean, through five consecutive CNI blood levels that are above or below the mean, and through five consecutive increasing or decreasing CNI blood levels. Mohammed, Worthington, and Woodall (2008) presented a simple example of using the *x*- and *mr*-charts for monitoring a patient's systolic blood pressure readings. The Exponentially Weighted Moving Average (EWMA) control chart was applied for the detection and diagnosis of hotspots for the enhanced management of hospital emergency departments in Australia (Bolt and Sparks 2013).

Tennant et al. (2007) systematically reviewed the use of control charts to monitor clinical variables in individual patients. Their systematic searches of eight databases yielded 74 studies, however, only 7 met their inclusion criteria of using control charts to monitor clinical variables for a disease at an individual patient level. In those papers, control charts were used to monitor four diseases: hypertension (Hebert and Neuhauser 2004; Solodky et al. 1998), asthma (Gibson et al. 1995; Boggs et al. 1998; Alemi and Neuhauser 2004; Hayati et al. 2006), renal function post-transplant (Piccoli et al. 1987) and diabetes (Solodky et al. 1998). The studies were either intended to access the performance of the control charts in comparison to existing "gold standard methods" or they were specific case studies. The excluded studies were review articles (i.e., Boggs 2005; Alemi and Sullivan 2001), applications not for monitoring individual patients (i.e., Bucuvalas et al. 2005; Milligan et al. 2002), etc.

2.2. The use of MSPM

The MSPM techniques may be fully combined with the patient's file record in order to monitor critical individual indicators of a patient-driven from a variety of diagnostic tests. Such methodologies are new and very innovative.

Zhang, Li, and Wang (2010) proposed a Multivariate EWMA (MEWMA) Phase II control chart for simultaneously monitoring the mean and variability that is based on the generalized likelihood ratio statistic. This control chart was applied to patients that were equipped with instruments that measure and record physiological variables like systolic blood pressure, mean heart rate, etc. Compared with several existing charts, this chart is significantly better in detecting almost all kinds of shifts in the process.

Correia, Nêveda, and Oliveira (2011) presented how univariate and multivariate control charts can be used for monitoring patients with chronic respiratory disease. The authors emphasized the fact that controlling several correlated variables simultaneously, using univariate control charts can be misleading. The authors constructed the T^2 multivariate charts with variables PaO2 and PaCO2, as well as PaO2, PaCO2, and BMI, to verify if differences owing to the BMI variable's influence are detected. They concluded that in the medical context where the aim is to detect changes in the mean solely in one direction (i.e., to detect improvement or deterioration of health), one-sided control charts are preferable.

Recently, Koutras and Sofikitou (2020) developed two semiparametric bivariate control charts that exploits order statistics. These control charts are effective when we jointly monitor possible shifts in the process mean and/or variance. The control charts were implemented on a breast cancer data set.

3. SPM applied in the health organization layer

One interesting extension of biosurveillance is the surveillance of medical variables at the health organization layer (e.g., hospital). This implies that the surveillance/monitoring targets to hospital-associated variables, such as infection rates, rates of patient falls, number of deaths, waiting time from surgery to full recovery, waiting time in the emergency room, etc.

Apart from hospitals and other healthcare provision structures such as nursing homes, private doctors, etc. there are also large organizations, which coordinate and supervise the delivery of healthcare services by the providers. In this context, monitoring variables such as expenditures, quality of care, providers' misbehavior, etc. can lead to better services.

3.1. The use of SPM

Benneyan (1998a, 1998b) published two papers discussing the application of SPM techniques to hospital epidemiology. The first paper (Part I) provides an overview of quality engineering and SPM while at the same time illustrates common types of control charts. The $\bar{X}$ and S charts can be applied in monitoring patient waits, procedure durations, the timing of preoperative antibiotics, other time intervals, various physical and physiological variables. The c and u control charts are appropriate for the number of patients falls per month, arrivals to an emergency room, maternity cases per week, and infectious diseases per time period. The np and p charts can be applied for monitoring the total number of catheters and other devices that result in associated infections, the fraction of complication-free coronary artery bypass graft surgeries, and the number or fraction of handlings of needles and other sharp objects that result in inadvertent sticks. The second paper (Part II) discuss statistical properties of control charts, issues of chart design and optimal control limit widths, alternate possible SPM approaches (the geometrically weighted moving average (GWMA) and the cumulative sum (CUSUM) control charts) to infection control, some common misunderstandings, and more advanced issues.

Lee (2002) presented a tutorial for the use of control charts and discussed four case studies: two for monitoring C-section rates in two hospitals, the monitoring of the number of falls per 100 resident days at a long term care organization, and the monitoring of the postoperative length of stay for coronary artery bypass graft patients.

Benneyan and Borgman (2003) presented an overview of SPM techniques and several applications of control charts in the healthcare field. More specifically, they presented the use of control charts for monitoring the flash sterilization rate, the monitoring of the laboratory turn around time, of surgical site infections, of the appointment access satisfaction, and the infectious waste monitoring.

An attempt to set up a syndromic surveillance system was made in Athens in 2004 during the Olympic Games (Dafni et al. 2004). The data analyzed were daily syndromic counts in emergency departments of four major hospitals in the Athens area during the period August 2002–August 2003. Among the techniques used was the CUSUM control chart.

Mohammed, Worthington, and Woodall (2008) showed the use of several typical control charts through simple examples. They used a p-chart to monitor the number of patients who were admitted with a fractured neck of femur and the number who died over 24 consecutive quarters while they used a u-chart to monitor the number of falls in a hospital department over a 13-month period. The u-chart was also used to monitor the number of emergency admissions over 23 consecutive Mondays to a large acute hospital (under the assumption that the events were of relatively low frequency in comparison to the size of the underlying population and that the size of the underlying population was unknown). Assuming that the underlying population was large and fairly constant, the same problem can be handled through a c-chart, which is essentially a u-chart with $n_i = 1, i = 1, 2, \ldots, n$.

Henderson et al. (2008) used the I control chart – a chart for individual values – to determine whether or not "special cause variation" followed known changes in stroke service structure and publication of the Medical Research Council (MRC) Heart Protection Study. Unexpected signals of special cause variation were identified and reasons for observed patterns were sought by a discussion with clinical teams. They concluded that SPM charts can provide valuable insights into the impact of changes in the structure of services and of clinical evidence in the quality of care.

Recently, Rakitzis, Weiß, and Castagliola (2016) modified the Shewhart and the CUSUM charts to monitor correlated Poisson counts with an excessive number of zeros using the zero-inflated Poisson distribution and appropriate integer-valued time series models. They applied the modified control charts for monitoring the monthly numbers of submissions to animal health laboratories from a region in New Zealand. Earlier, Fatahi et al. (2012) had developed an EWMA control chart for monitoring rare health-related events with a predefined performance measure value.

Earlier, Lovegrove et al. (1997, 1999) and Poloniecki, Valencia, and Littlejohns (1998) independently proposed cumulative plots for the expected mortality counts minus the observed counts that could be applied, for example, to physicians or hospitals. The Variable Life Adjusted Display (VLAD) chart, that Lovegrove et al. (1997) presented depicts the risk-adjusted survival figures for individual surgeons or units over time and could be modified to monitor performance over a range of treatments and outcomes. The VLAD chart was recently applied in order to monitor the risk-adjusted 30-day mortality and morbidity following cardiac surgery (Ananiadou et al. 2020).

As we noted in the previous section, the input unit in healthcare is mainly the patient and his/her characteristics. However, the characteristics of the patients may enormously differ (Alemi and Sullivan 2001). This means that even when the patients have the same disease, they differ considerably by the severity of the disease and prognosis of their illness. Thus, the control charts should be adjusted to take into account patients' different characteristics. Alemi and Sullivan (2001) described the use of a risk-adjusted $\bar{X}$-chart in order to reduce the cesarean section rates. Such a control chart compares observed rates to what could have been expected from the women's pregnancy complications.

Earlier, Steiner, Cook, and Farewall (2000) had proposed a risk-adjusted CUSUM control chart that adjusts for each patient's pre-operative risk of surgical failure through the use of a likelihood-based scoring method. More specifically, they adjusted the CUSUM control chart based on prior risk by adapting the magnitude of the scores using the patient's surgical risk, estimated pre-operatively. The surgical risk varies for each patient depending on risk factors present.

Chen and Huang (2014) proposed a CUSUM residual chart in order to detect the outbreak of the respiratory syndrome in Taiwan. They first used a regression model with an autoregressive integrated moving average (ARIMA) error term to model the daily counts of ambulatory-care clinic visits. Then they plotted the CUSUM of residuals on a CUSUM chart to detect any unusual increases in the number of daily visits.

A number of types of control charts have been modified to adjust for risk. In order to assess the quality of care that health organizations offer, Alemi, Rom, and Eisenstein (1996) presented risk-adjusted control charts that take into account the severity of illness of the hospital's patients during different time intervals. Poloniecki, Valencia, and Littlejohns (1998) described the use of a risk-adjusted CUSUM chart to detect changes in mortality after heart surgery while Steiner, Cook, and Farewall (1999) and Steiner, Cook, and Farewell (2001) presented risk-adjusted CUSUM charts for monitoring paired binary surgical outcomes. The CUSUM chart is based on likelihood ratios and these ratios are affected by the varying in-control probabilities of mortality for patients. Gustafson (2000) proposed new charts based on the Standardized Infection Ratio, which are risk-adjusted, and perform satisfactorily with small denominators. Spiegelhalter et al. (2003) investigated the use of the risk-adjusted sequential probability ratio test while Cook et al. (2003) presented risk-adjusted control charts for prospectively monitoring outcomes in the intensive care unit. Benneyan and Borgman (2003) discussed the importance of integrating risk-adjustment to methods such as the control charts, the sequential probability tests, and other surveillance methods. Grigg and Farewell (2004) presented a practical overview of risk-adjusted control charts while Beiles and Morton (2004) described the use of CUSUM control charts (odds CUSUM and counted data CUSUM) for assessing performance in arterial surgery. CUSUM techniques have also been used in Australasia in assessing the competence of trainees and in the area of infection control (Bolsin and Colson 2000). Woodall, Fogel, and Steiner (2015) presented an overview of risk-adjusted methods for monitoring medical outcomes with an emphasis on the quality of the surgery process. A recent review paper on the theory and applications of risk-adjusted control charts is the one by Sachlas, Bersimis, and Psarakis (2019).

I-MR charts were used to analyze the length of stay on diabetic inpatients in two hospitals: a teaching hospital in the USA, and a teaching and research hospital in Turkey (Pakdil, Azadeh-Fard, and Esatoglu 2019). p-charts were used to monitor the percentage of elevated lead levels among patients 9–27 months old at an academic primary care center in the USA (Brown et al. 2019). This increased provider adherence with published guidelines.

In the context of the proper functioning of a hospital, the c-chart was applied to check whether the optimum allocation of 252 general nurses to 15 wards in a hospital in Nigeria was in control or not (Odinikuku, Ikimi, and Onwuamaeze 2019).

Recently, Fatt Gan, Sheng Yuen, and Knoth (2019) developed a new class of risk-adjusted CUSUM procedures for monitoring surgical processes. The advantage of this class is that it is updated on a regular basis based on patients' current conditions; thus researchers do not have to wait 30 days after the surgery to record the outcome.

The use of SPM techniques has also been discussed in several books, including Carey and Stake (2003), Hart and Hart (2002), and Morton (2005).

3.2. The use of MSPM

MSPM techniques have been applied to healthcare organization processes, with the aim of ensuring their proper functioning. In order to improve the quality of healthcare services, several researchers have developed or simply used multivariate control charts.

Aiming at the best possible care, Dechert and Case (1998) used the T^2 multivariate control chart as an alternative method of ensuring the quality of care of a clinical laboratory in the case of correlated control concentrations. Steiner, Cook, and Farewall (1999) proposed a bivariate CUSUM for monitoring failure rates in the treatment (more specifically in pediatric surgeries) of a hospital.

Hart et al. (2003) proposed a new class of control charts of reducing and improving the quality of care. These are risk-adjusted, time-ordered control charts capable to reduce time-to-time variation that may stem from uncontrollable changes in the patient mix over time. Multivariate logistic regression models were used to compute risk-adjusted rates. The new charts were applied for a 2-year period using monthly rates on three different sets of data: low birth weight, mortality, and Cesarean section.

Webster (2008) in his PhD thesis dealt with the development of risk-adjusted statistical methods for the surveillance and monitoring of adverse hospital events.

Grigg et al. (2009) proposed a signaling procedure to control the false discovery rate (i.e., the proportion of all alarms detected that are false). They applied local and marginal control charts (the Shewhart chart, EWMA chart, and tabular CUSUM) to methicillin-resistant Staphylococcus aureus bacteremia reports in UK acute National Health Service trusts.

Waterhouse et al. (2010) discussed the implementation and performance of three multivariate control charts, i.e., the T^2, the MEWMA, and the MCUSUM for monitoring radiation transmitted in patients undergoing diagnostic coronary angiogram procedures. They concluded that MEWMA and MCUSUM charts detect small to moderate shifts quickly, even when the quality characteristics are uncorrelated while the T^2 chart performs less well overall, although it is useful for the rapid detection of large shifts. In the case of incomplete records, which is common in medical practice, the authors recommended the use of multiple imputation.

Spiegelhalter et al. (2012) discussed three interrelated regulatory strategies for rating, screening, and surveillance of healthcare organizations. Control charts such as the EWMA chart and the VLAD chart were used to monitor more than 200,000 indicators for excess mortality.

Shojaei and Niaki (2013) proposed a modified MCUSUM chart for monitoring multi-attribute medical processes for entities that have different levels of risk in a hospital. The risk-adjusted multivariate cumulative sum control chart (RA-MCUSUM) takes into account the heterogeneity in patient conditions which lead to different prior levels of risk at the time of treatment. A simulation of a medical system with three groups of entities (low, medium, and high) was used to assess the performance of this chart.

Maruthappu et al. (2014) used patient-adjusted and fully adjusted (adjusted for patient risk and surgeon experience together) multivariate control charts for monitoring individual operative efficiency. The two control charts were compared through the analysis of 5,313 knee replacement procedures performed by 17 surgeons at a single academic tertiary care center in the USA. Also in the surgical context, Abdollahian, Ahmad, and Huda (2011) applied and compared univariate and multivariate (i.e., the T^2) control charts for monitoring three correlated quality characteristics simultaneously.

Harrou et al. (2015) proposed a PCA-based MCUSUM anomaly detection system for monitoring patients flows in the pediatric emergency department of a hospital center in France. This chart is applied to the residuals obtained from the Principal Components Analysis (PCA) model to detect anomalies when the data did not fit the PCA model.

Bersimis, Sachlas, and Castagliola (2017) presented a method of controlling bivariate categorical processes using scan rules. More specifically, they considered a sequence of independent identically distributed bivariate random variables, related to the postoperative condition of the patient with three possible outcomes: "absolutely successful," "with minor but acceptable complications" and 2 "unsuccessful due to severe complications." The authors, using a 2-dimensional *moving window* of a specific length, assumed that the process is declared as out-of-control with the first occurrence of either one 2 in either of the two components or k 1's in a 2-dimensional *moving window* of length ℓ containing only 0 and 1. They explored the performance of this rule by exploiting the run length distribution. From a mathematical point of view, they focused on modeling bivariate sequences of trinomial trials and on studying the random variable S related to the waiting time until the first occurrence of a 2-dimensional scan of type k/r of patients experiencing mild complications or of a patient with severe complications. To calculate the exact distribution of the waiting time variable S they used the Markov chain embedding technique.

Bersimis, Sachlas, and Sparks (2017) proposed a procedure based on an appropriate control chart in order to monitor health service performance using more than one performance outcome variable and to assess the competence among health practitioners. They used the Markov Chain embedding technique to study the exact distribution of interest and they introduced the necessary details for applying risk adjustment in monitoring two health practitioners' performance.

Recently, George et al. (2019) accessed interventions to reduce the percentage of patients with medication errors during discharge. The p-chart was applied to monitor the percentage of patients with prescribing error and the number of discharged patients. The intervention program successfully attained a high percentage of patients with medication errors that was intercepted and corrected at discharge.

3.3. Combination of SPM and MSPM methods with other techniques

As discussed by Lawson (2006), it is often desirable to incorporate spatial information into a monitoring procedure to detect clusters of disease. In order to take into account the area dimension, control charts are used in conjunction with area control techniques such as the spatial scan technique (Kulldorff 1997; Kulldorff et al. 2007).

The EWMA procedure was successfully combined with scan statistics (Sparks 2012). As scan statistics examine space-time block counts for a moving time window of days, the author used the EWMA of the counts using a multiple scan plan. Furthermore, Sparks and Patrick (2012) proposed a spatio-temporal EWMA-ordered scan statistic with homogeneous spatial expected counts in order to detect outbreaks that vary in size and shape.

4. SPM applied in the community layer

In the framework of public health monitoring, the use of SPM methodology has now become very popular across the world and especially in the USA. This is due in no small part to the World Trade Center attacks and the anthrax-laden letters that followed in October 2001. Large-scale bioterrorism now seems likely, if not inevitable, and syndromic surveillance, although largely untested, provides hope of a precious few hours or days of early warning. Surveillance does not refer only to terrorism or to outbreaks of infectious diseases, but also to the case of monitoring the levels of chronic diseases.

4.1. The use of SPM

Sonesson and Bock (2003) provided an excellent review paper on prospective statistical surveillance in public health. They highlighted some of the problems and issues related to the statistical evaluation of the proposed methods. There is, for example, very little use of steady-state run-length performance of proposed Phase II methods in the public-health surveillance literature (Woodall 2006).

According to Woodall (2006), CUSUM charts are widely used in healthcare monitoring and in public health surveillance in contrast with the Exponentially Weighted Moving Average (EWMA) chart, which is rarely used. Usually, in healthcare, the CUSUM charts are one-sided, with the part corresponding to process improvement or a decrease in a disease or mortality rate not included. CUSUM charts have also been proposed for the monitoring of adverse reactions to drug treatments (Praus et al. 1993), to assess trainee competence (Bolsin and Colson 2000), and in the detection of bioterrorism (Hutwagner et al. 2003, 2005, 2005).

Most of the CUSUM charts applied in the health-related SPM literature are Poisson-based CUSUM charts for count data (Ewan and Kemp 1960; Lucas 1960). The CUSUM charts for exponential random variables (see e.g., Vardeman and Ray (1985)) have been used for monitoring rates of congenital malformations under the assumption of a constant birth rate. For mortality-rate monitoring, Rossi, Lampugnani, and Marchi (1999) proposed a way of overcoming the constant in-control parameter assumption for the usual Poisson CUSUM by basing the CUSUM on standardized counts, subtracting from each count the in-control mean and dividing by the in-control standard deviation.

O'Brien and Christie (1997) presented the CUSUM technique as a useful supplement to other surveillance methods in infection control. They presented two examples: one for monitoring mycoplasma pneumonia and one for monitoring rubella. In both cases, the CUSUM control chart signaled long before the change in incidence was evident.

VanBrackle and Williamson (1999) examined the statistical properties of various control charts for the detection of unusual patterns of reported cases of diseases from the Centers for Disease Control and Prevention's National Notifiable Diseases Surveillance System. The average run length characteristics of the control charts were studied through simulation and analytical techniques and the authors concluded that the average run lengths for the highly correlated disease series are much longer than in the usual independent data case.

Williamson and Hudson (1999) presented a two-stage monitoring system incorporating statistical "flags" identifying unusually large increases (or decreases) in disease reports compared to the number of cases expected. It consists of univariate Box-Jenkins models and subsequent tracking signals from several statistical process control charts. The system was applied to the United States disease report series.

Perhaps the only paper that discussed the use of EWMA control charts in a healthcare setup is that of Morton et al. (2001). According to the authors, the Shewhart type chart detects large deviations, while the CUSUM and EWMA charts are more sensitive in recognizing small to moderate deviations. The combination of Shewhart and EWMA charts are ideal for monitoring bacteremia and multiresistant organism rates, while Shewhart and CUSUM charts are appropriate for surgical infection surveillance.

Grigg, Farewell, and Spiegelhalter (2003) discussed the use of three control charts, which are based on the sequential probability ratio test (SPRT). These are the CUSUM chart, the resetting SPRT (RSPRT) chart, and the fast initial response (FIR) CUSUM chart. The underlying assumption of these charts is that the in-control probability of death, for example, can vary from person to person according to an assumed model. Grigg and Farewell (2004) presented a review of risk-adjusted control charts (CUSUM, RSPRT, the sets method, and Shewhart chart). Their comparison showed that the CUSUM is the least efficient, under the average run length (ARL) criterion, of the RSPRT. Furthermore, the sets method is more efficient than CUSUM, for binary data, when the in-control ARL is small and more efficient for a slightly larger range of in-control ARLs when the change in the parameter being tested for is larger. The Shewhart *p*-chart was found to be less efficient than the CUSUM even when the change in the parameter being tested for is large.

Lin, Tsui, and Lin (2014) proposed the spatial-EWMA procedure for detecting and locating the centers of the shifted areas. This procedure assigns different weights to the data with different radius levels from the investigated shift center.

Bersimis and Economou (2017), motivated by the case of a possible sampling mechanism changes from Phase I to Phase II, proposed a control charting procedure where there is a change of the monitored statistics from phase to phase and where the Phase II control chart is based on the harmonic mean.

The diversification of sampling mechanisms appears frequently in public health monitoring and syndromic surveillance. This chart is easy to apply and detects even small shifts in a quick and accurate manner.

Bersimis, Degiannakis, and Georgakellos (2017) proposed an advanced modeling scheme for real-time monitoring of pollution data, a case that is closely related to public health. This scheme exploits an appropriately adjusted multivariate time series model used mainly in finance and a control chart based on the components derived after applying dynamic principal component analysis (DPCA) on the output of the time series for the early detection of abnormal increases of CO levels. The proposed methodology was applied in the city of Athens showing a very good performance.

Recently, Bersimis, Sachlas, and Economou (2019) presented a new monitoring procedure for monitoring at the same time the number of disease events through control charting and the spatial distribution of disease events through convex hulls.

Hall and French (2019) argued that, in a disease surveillance setting, resetting the CUSUM statistic is unrealistic; thus, they proposed a non-restarting CUSUM chart. This chart has the ability to monitor a continuous outbreak, while at the same time, it reduces the number of postoutbreak false alarms.

4.2. The use of MSPM

Fricker and Rolka (2006) applied simultaneous univariate CUSUM charts and a multivariate CUSUM method to identify increases in disease incidence while Fricker (2007) constructed two directionally sensitive multivariate procedures for syndromic surveillance. They also introduced the notion of the average overlapping run length (AORL) for comparison of the performance of various procedures on limited actual syndromic surveillance data. The application of CUSUM control charts for disease surveillance have been also discussed by Tsui, Jiang, and Mei (2010).

Rogerson and Yamada (2004) compared multiple univariate CUSUM charts with a directionally invariant multivariate CUSUM for monitoring changes in spatial patterns of disease. They illustrated the methods on simulated data and on county-level data on breast cancer concluding that when the spatial autocorrelation is low, the univariate method is generally better at detecting changes in rates that occur in a small number of regions while the multivariate is better when change occurs in a large number of regions.

The up to date procedures are aiming at multiple characteristics/type of diseases/events/in general variables, take into account the probable structure among the variables (Lotze, Shmueli, and Yahav 2007), model the autocorrelation (Burkom, Murphy, and Shmueli 2007), treat the spatial nature of the problem (Lawson 2006; Sparks, Keighly, and Muscatello 2009; Sparks et al. 2009; Sparks 2010), and are capable of choosing the appropriate characteristics to monitor (Mostashari et al. 2003). In most cases control charts are used in conjunction with the spatial scan statistics (Shmueli and Burkom 2010; Sonesson and Bock 2003; Woodall 2006; Woodall et al. 2008). Despite the flood of interest, many questions need further investigation, for example: Which is the normal behavior in order to identify the presence of abnormal behavior? Which stochastic models perform better in outbreak detection and which perform better in monitoring rates of chronic diseases? Which is the effect of correlation and which is the effect of the number of characteristics that are monitored? Which procedure is the best for selecting the appropriate characteristics that you track? Do parametric control charts provide an appropriate framework for our problem or non-parametric control charts should be practiced?

Frisén, Andersson, and Schiöler (2010) discussed the special challenges regarding the evaluation of multivariate surveillance methods, suggested some new measures and demonstrated the properties of several measures. A semi-parametric model for multivariate outbreak detection was presented by Schiöler and Frisén (2012).

Joner Jr et al. (2008) presented a multivariate EWMA chart for detecting a rise in the incidence rate of disease. This multivariate chart is effective whenever the disease appears in different regions. Rolka et al. (2007) discussed several multivariate statistical techniques in the field of public health surveillance for emerging threats. Miekley et al. (2013a), and Miekley, Traulsen, and Krieter (2013b) used multivariate control charts to detect mastitis and lameness as early as possible. Mertens et al. (2011) reviewed several applications of control charts for livestock data dealing with univariate charts. It is really interesting to apply MSPM techniques in livestock data. Yahav and Shmueli (2014) used multivariate control charts for detecting disease outbreaks.

Recently, Bersimis, Sachlas, and Papaioannou (2018) proposed flexible designs for monitoring phase II clinical trials in which two treatments are compared with respect to two dependent dichotomous responses (successful or not). Pairs of two patients enter the clinical trial sequentially and each patient is randomly assigned to two treatments: the standard and the experimental one. The clinical trial stops in favor of the experimental treatment when a total of k cases showing improvement due to the experimental treatment in at least one of the characteristics are observed early enough while it stops in favor of the standard treatment when a total of k cases showing improvement due to the standard treatment in at least one of the characteristics are observed early enough. Finally, the clinical trial stops with a decision that the two drugs are equivalent when a total of k cases showing improvement due to the standard treatment or due to the experimental treatment are not observed early enough. The "early enough" means before the c-th pair of patients. The proposed designs were defined on bivariate sequences of multistate trials, and the corresponding stopping rules were based on various distributions related to the waiting time until a certain number of events appear in these sequences. The exact distributions of interest were studied using the Markov chain embedding technique. For other aspects of community surveillance, such as the monitoring of pharmaceutical, diagnostic, clinical safety and food safety, the reader is referred to the review paper of Bersimis, Sgora, and Psarakis (2018) and the references therein.

Recently, Liu et al. (2019) proposed an EWMA control chart based on rank methods to be used for multivariate processes. This control chart was applied in a large time–series of the weekly incidence of influenza in Japan showing that the control chart has a good performance for detecting process changes (especially, small shifts).

5. The Proposed Framework

As already mentioned, the SPM toolbox can be used in order to monitor the public health as well as a wide range of medical variables at the hospital level. Furthermore, another extension that the SPM toolbox can be used is the monitoring of a single patient. Thus, in this Section, we propose a three-layer framework of the application of the SPM toolbox in Health. The proposed framework is represented graphically in Figure 1, in the form of a pyramid. Specifically, the first layer of the framework requires the "Personalized Monitoring of Citizens' Health" by feeding continuously in time their medical data from their medical records into an appropriate software system that would be able to process the data in real-time using SPM techniques and giving early alarms in cases of suspect changes in the personalized distribution of these variables appear. This is the Base Layer of the framework.

Citizen Layer The purpose of implementing the SPM techniques on the individual patients and healthy persons' health indicators (e.g., cholesterol levels, blood pressure, etc.) is to timely detect risks. This objective is achievable given that SPM techniques can recognize even the slightest variation in the state of the ongoing process (assuming that patient's or healthy people's health is a process). This layer of the framework requires people to have medical records, which is valid for the greatest percentages of the population in most countries

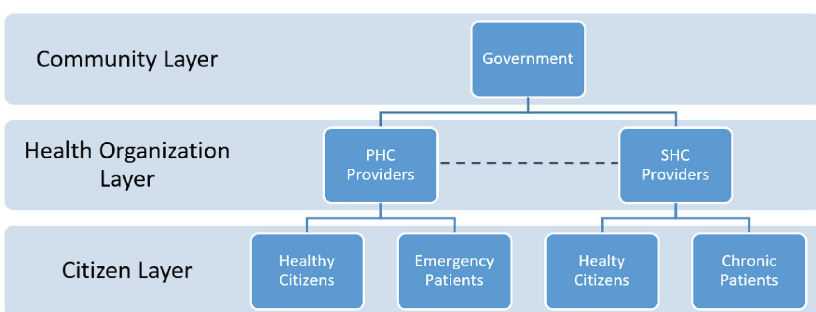


Figure 1. The unified framework for public health based on SPM and MSPM.

of the developed world. An exception is some categories of people such as the homeless, the mentally unwell, etc. However, these categories of the population are very small percentages of the total population.

Health Organization Layer The second layer of the framework (see Figure 1) requires the "Hospital's Processes Monitoring", i.e., most crucial hospital's processes will be monitored – mainly medical and secondary managerial – in order to boost the quality of hospital's (or any other healthcare services provider) services. This is the Intermediate Layer of the framework. Except for data coming internally from the intermediate layer (e.g., in-patient data), the framework at this layer will also use the information produced by the framework at the first layer (out-patient data).

The aim of applying the SPM techniques to all of the organization's processes is to detect possible risks in the healthcare organization's premises (e.g., medical errors, rates of contamination, etc.), to improve the services provided to patients (e.g., the time of laboratory tests, patient service time, patient satisfaction indicators, etc.) as well as the improvement of finances through the constant monitoring of financial data (e.g., consumption of specific consumable items, drug consumption, etc.). In summary, by improving the quality of services provided by a health organization, we achieve a high level of patient safety, procedures' efficiency, strict control over the consumption of available resources, and comparability of the performance of organizations. Furthermore, if the quality of services provided by a health organization to a patient improves, as a result, the quality of life of the patient also improves.

Community Layer The third layer of the framework (see Figure 1) requires the "Community Monitoring" (e.g., virus related events will be continuously captured by the system as well as non-virus related events will be tracked in order to explore the possible high prevalence of virus-related diseases, blood pressure, of diabetes, etc). This is the Top Layer of the framework. Except for raw data, the system, at the Top Layer, will also use the information produced by the framework at the Base and Intermediate Layers, in order to enhance its power to detect outbreaks of infectious diseases or increasing trends in the rates of chronic diseases.

The implementation of SPM methods on cases of specific diseases aims at early detection of possible outbreaks of infectious diseases or the increase in the prevalence of noninfectious, possibly chronic and/or malignant diseases, and at early detection of changes in patient behavior in order to make appropriate interventions. Improving the quality of public health as a whole, we achieve a sense of security in society and even tighter control over the consumption of available resources (e.g. antibiotics).

Interactions Among the Layers It is evident that in order for the proposed framework to achieve its aims, the 3 layers should be interconnected (Figure 2); each layer should feed data to the others. For example, beginning from the

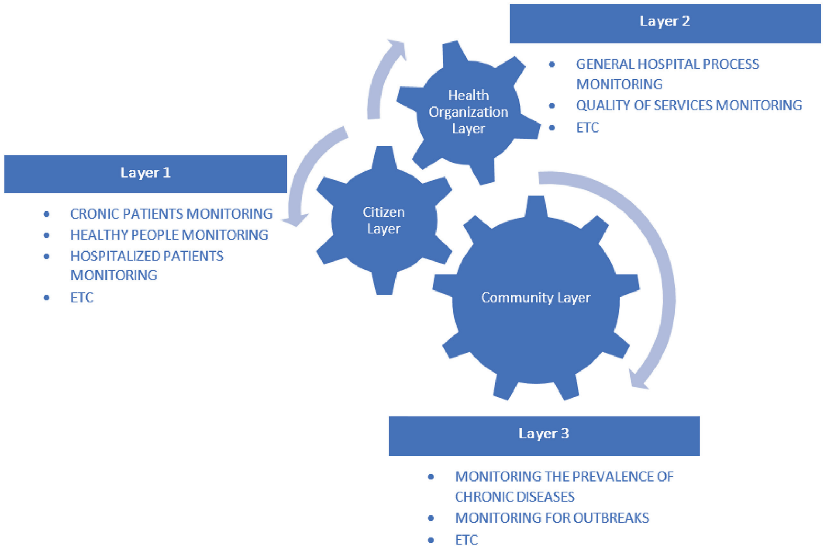


Figure 2. The three layers of the unified framework in which SPM and MSPM can be used.

first layer, the SPM techniques will notify physicians in time for either out-of-control measurements or ascending/descending measurements indicating a dominant disease state. This means that physicians will provide better health services at the primary level. As long as these measurements indicate the necessity of hospitalization, physicians would have the opportunity to perform the necessary procedures for the timely hospitalization of the patient. This means better hospitalization planning, timely detection of problems, and better health services at the secondary level. The in-time detection of an event (or many events in the case of an epidemic) and the in-time and efficient hospitalization of the events protects the public health (third layer). Conversely, the activation of the public health surveillance mechanism activates healthcare organizations, protecting in this way the citizens' health.

Technical Specifications The implementation of stochastic data monitoring and processing models requires the creation of an appropriate information system that will receive or retrieve data, store and process them (using appropriate stochastic models), and produce results and additional information that will appear in a properly configured user interface. The information system to be developed should have a number of special features that will ensure its reliable operation, its usability, and its efficiency in data processing and inference. To meet the above requirements, the system will be based on a multi-tier architecture, which will allow changes to any of the levels, e.g., in the input data, without affecting the other.

The detailed description of the information system is out of the scope of this paper. In brief, the architecture of the system consists of four levels. The first one concerns the extraction and collection of data from health/hospital

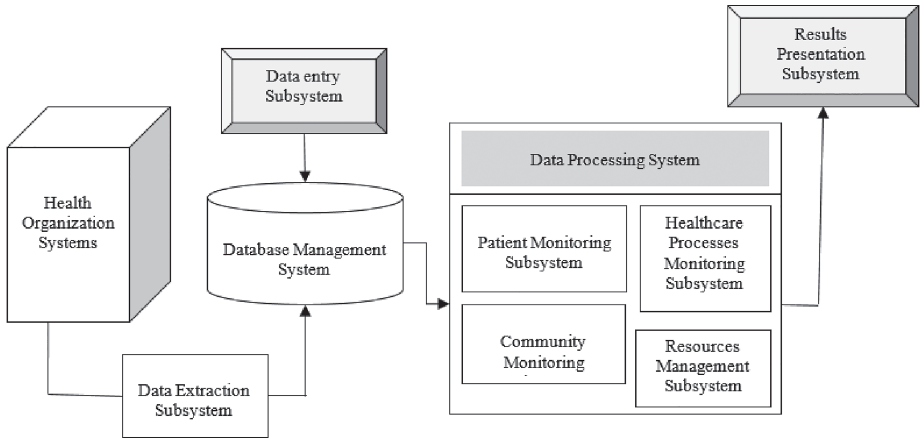


Figure 3. An indicative architecture of the system.

systems or data entry interfaces. The data will be entered into the system after an appropriate procedure of anonymization is applied and coded. At the second level, the data will be stored in a properly designed and configured database. At this level, detection of unexpected, incorrect and inconsistent data, correction or removal of incorrect data, and verification of their correctness will take place. At the third level, the data will be analyzed using algorithms applied to stochastic models. The processing of the data will lead to the production of information, which will be displayed, at the fourth level, in an integrated user interface. An indicative architecture of the system is described in Figure 3.

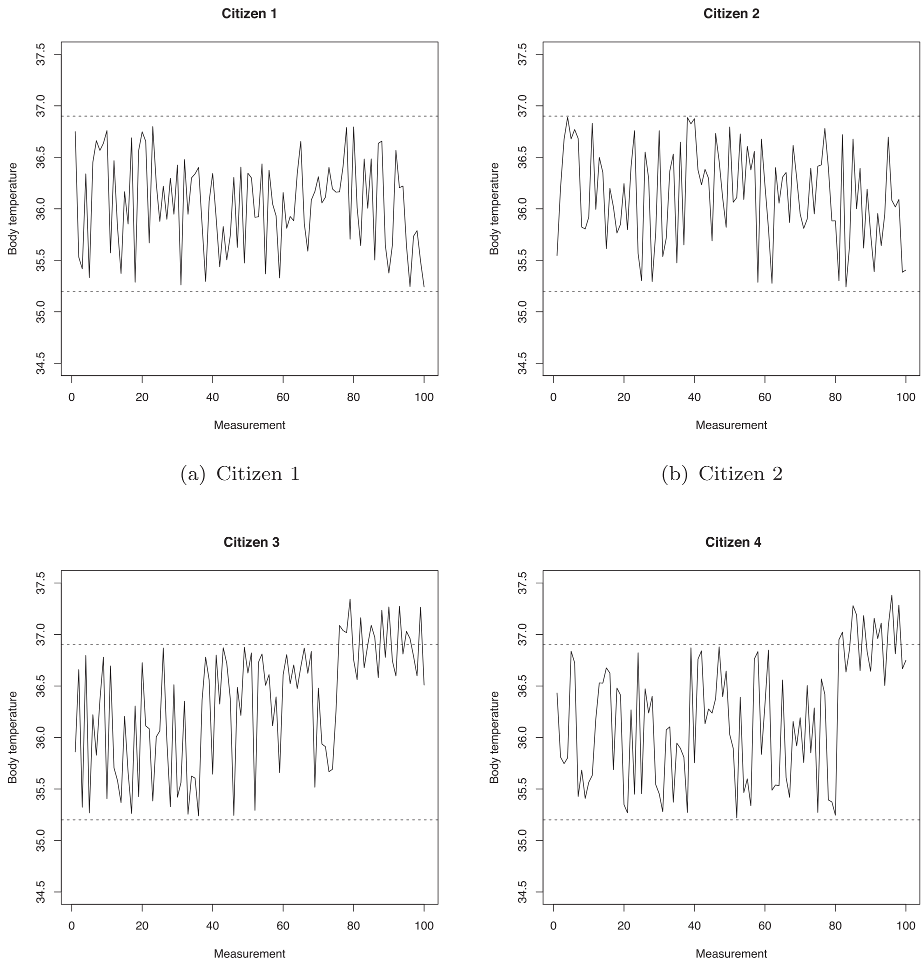
Discussion on the Framework All the above may be successfully realized, only after in-depth research of the worldwide literature in order to identify the most appropriate indexes or even initiate new ones corresponding to each one of the processes that will be monitored (patient health, hospital's functionalities, community's health).

The purpose of the paper is to justify that such a framework is feasible by reviewing the literature and presenting justification of this feasibility. Actually, as we have shown in the previous sections, the SPM toolbox is already applied in these three layers while the only thing that is needed is the appropriate software system that could record and process these data in real-time.

Thus, the proposed framework enhances the ability of public health infrastructures to detect, investigate, and respond to both disease outbreaks and early detection of people's illness. This means that the proposed framework ensures "Public Health."

6. A Simulation of the Framework Operation

In this section, we will present a simulated example of the framework's operation.



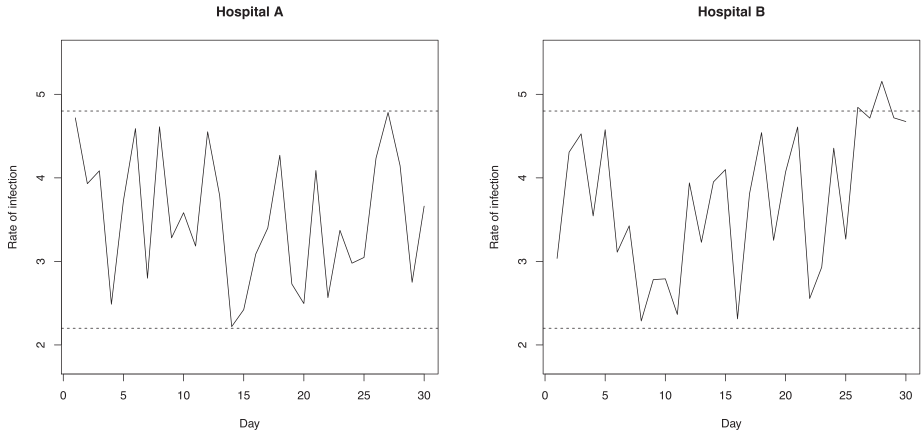
(a) Citizen 1 (b) Citizen 2

(c) Citizen 3 (d) Citizen 4

Figure 4. Shewhart type control charts for the monitoring of the body temperature of four citizens.

Citizen Layer Let assume that we monitor the body temperature, which is among the Coronavirus COVID-19 symptoms, of the adult population of a village. The normal range of body temperature for adults is 35.2–36.9°C. Figure 4 indicatively shows the control charts for four citizens of the village. It is obvious that the body temperature of Citizens 1 and 3 whose control charts appearing in the first line of the figure lies within the normal range. On the contrary, Citizens 3 and 4, whose control charts appearing in the second line of the figure, on their latest measurements, show body temperature greater than permissible, which is a sign that they should be further monitored and possibly hospitalized.

Knowing the number of citizens with abnormal body temperature, as well as the severity of their condition, the hospital or hospitals of the area can be appropriately organized to deal with a worse situation.



(a) Hospital A (b) Hospital B

Figure 5. *p*-charts for the monitoring of the rate of patients experiencing a hospital infection into two hospitals.

Health Organization Layer Let assume that citizens are admitted to hospitals in the area with high body temperature and we monitor the rate of patients experiencing a hospital infection or appear another Coronavirus COVID-19 symptom. Figure 5 shows the control charts for the two hospitals. The process for the Hospital A is in-control, i.e., the rate of hospital infections is within the acceptable limits. On the contrary, for Hospital B, we observe that in the last five days the rate of hospital infections was increased and in some days exceeded the maximum permitted limit. Thus, the hospital management and/or the government should investigate if this is due to a hospital malfunction or to some other illness-related event.

Community Layer Let assume that we monitor the number of citizens appearing symptoms of high body temperature. From the CUSUM control chart of Figure 6 we observe that the cumulative sums begin to pile up after Day 25 and continue until the control limit is exceeded on Day 27. This is a sign that the number of cases in the area is increasing and the government should take action to prevent the problem from escalating further.

7. Discussion

The world today is experiencing an unprecedented situation due to the pandemic of Coronavirus COVID-19 with unknown consequences. Thus, developing a systematic way of collecting and analyzing health risk factors is essential for their effective use in the design of each country's health policies, but also for their comparative evaluation across countries, and has a number of beneficial effects on quality of life of people in society.

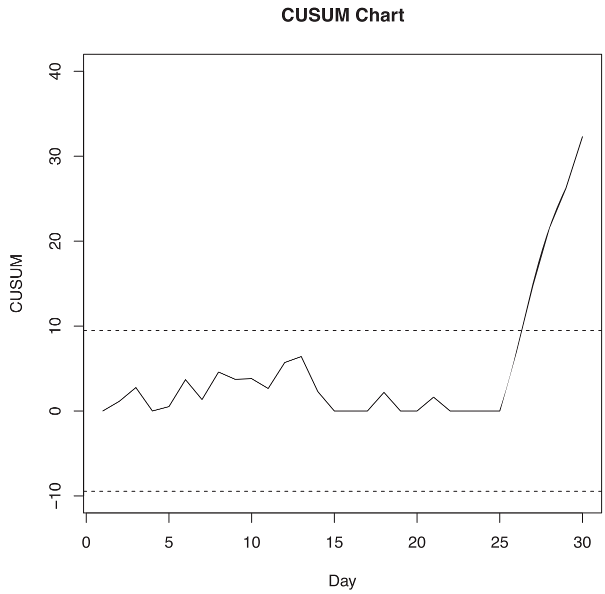


Figure 6. A CUSUM control chart for monitoring the number of citizens appearing symptoms of high body temperature.

Han et al. (2010) compared through simulations and real data the CUSUM and EWMA charts, concluding that the CUSUM charts were superior when we deal with a large shift with a later change in time. On the other side, the EWMA charts had a better performance than the CUSUM charts in cases of small shifts and an early change in time.

The control charts, the basic tool of SPM, is widely used for monitoring health processes. In this paper, we presented the basic uses of the control charts into three layers: the citizen layer, the health organization layer, and the community layer. Given that SPM techniques are already used in these three layers, we then proposed a hierarchical framework for the surveillance of public health. The framework consists of these three layers (Figure 1). We start from the patient layer (i.e., monitoring of individuals (both ill and healthy citizens) health indicators). We then move to the health organization layer in order to improve the services provided by Secondary Health Care Providers (SHC) and Primary Health Care Providers (PHC) to patients by monitoring all the necessary processes (services, financial data, etc.). Finally, we end up at the community layer, where the main objective is governments to early detect possible disease outbreaks.

The combined use of SPM and/or MSPM techniques, and especially, control charts, at all three layers will be a significant advance in ensuring the citizens' good health status, and the provision of high-quality health services. These will lead to a high level of public health. Besides, this is demonstrated by the use of such techniques in individual cases as evidenced by the review presented in this paper.

Control charts can be used in the daily management of healthcare processes to analyze routinely collected data and reduce "management by opinion," as in the cases of flash sterilization and laboratory turn around time. Control charts can help policy makers avoid wasted investments in changes that sound good but do not actually deliver, as was the case in the surgical site infection example. That case further illustrated how control charts might be able to detect statistically significant signals from the patterns in the data more quickly than with traditional statistical methods. The appointment access satisfaction example illustrated the general application of control charts for conducting rapid screening experiments as an efficient prelude to a more traditional experiment. The infectious waste example illustrated the advantage of control charts for a layperson to see the statistical significance of both the shift in the mean and the change in the variability of the measurement under study (Benneyan and Borgman 2003).

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