Some Current Directions in the Theory and Application of Statistical Process Monitoring

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The purpose of this paper is to provide an overview and our perspective of recent research and applications of statistical process monitoring. The focus is on work done over the past decade or so. We review briefly a number of important areas, including health-related monitoring, spatiotemporal surveillance, profile monitoring, use of autocorrelated data, the effect of estimation error, and high-dimensional monitoring, among others. We briefly discuss the choice of performance metrics. We provide references and offer some directions for further research.

Key Words: Control Chart; Healthcare Monitoring; Image Monitoring; Profile Monitoring; Public-Health Surveillance; Risk-Adjusted Monitoring; Spatiotemporal Surveillance; SPC; Statistical Process Control.

1. Introduction

A GREAT deal of research has been done recently in the general area of statistical process monitoring. In addition, the range of applications has expanded greatly. We review some of the major application areas in our paper. Because the number of papers and books is far too large for us to provide a comprehensive listing or review, we rely to the extent possible on nearly 50 more specialized review papers published in the last 10 years. These review papers often contain research ideas at a more detailed level than we can provide in our broader overview.

Our paper can be considered to be a follow-up to that of Woodall and Montgomery (1999), so we try to avoid duplication of the material and references listed in that paper. Some of the areas we review,

such as profile monitoring, for all practical purposes did not exist in 1999. Work in some areas with less impact in practice seems to have slowed, for example, in the economic design of control charts, so we do not review these areas.

The methods we review have the following three characteristics: the collection of data over time, the desired quick detection of specified process changes due to assignable causes, usually represented by changes in the parameter(s) of a probability distribution representing the common cause variation in the process, and the specification of in-control performance measured by the false-alarm rate or other metric.

Process monitoring involves two phases. In Phase I, the practitioner collects a sample of time-ordered data from the process of interest. These Phase I data are used to gain process understanding. The practitioner must check for unusual or surprising results. In addition, the practitioner must assess the stability of the process, select an appropriate in-control model, estimate the parameter(s) of this model, and determine the design parameters of the monitoring method to be used in Phase II. The monitor-

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ing method is then implemented with data collected successively over time in Phase II in order to detect changes in the process from the assumed in-control model.

In many applications, it is possible to adjust processes using feed-forward or feedback control. In order to do this, there must be an adjustment variable with some information available on its effect on the response of interest. These applications are obviously important, but do not fall within the scope of our paper. For information and perspectives on this topic, we refer the reader to del Castillo (2002), Box et al. (2009) and Box and Narasimhan (2010). In addition, we do not cover prognostics (see Tsui et al. (2013)) or any batch monitoring applications in chemical-engineering processes, an area reviewed by Qin (2003) and Ferrer (2014).

There have been some general overviews of statistical process monitoring. Stoumbos et al. (2000) provided a review article on the more traditional methods for statistical process control (SPC) and changepoint detection. Nair et al. (2000) did a remarkable job of identifying two areas that have since received considerable attention, i.e., the monitoring of functions, now referred to as "profile monitoring", and surveillance with spatiotemporal data. Each of these areas is briefly reviewed in our paper. In addition, Frisén (2009) provided an excellent overview of methods, evaluation criteria, and application areas. One nontraditional application discussed in her paper was the monitoring of financial data, a topic covered in more detail by Frisén (2008).

We give overviews of work in various areas in the remainder of our paper. Our perspective is shared. The ordering of the topics is somewhat arbitrary. Given the scope of our review, we realize that we have undoubtedly missed some important papers and ideas. Our review is no doubt biased toward our own research interests. Many topics span two or more areas, so, in some cases, the division of material is somewhat arbitrary. We provide recent references so practitioners and researchers interested in learning more about the topics can more easily navigate the extensive literature. Ryan (2011) and Montgomery (2013) provided introductory descriptions of some of the areas with additional references.

2. The Role of Process Monitoring

It is important to put the role of process monitoring into perspective. We believe that process mon-

itoring is important to understand the variation in a process and to assess its current state. Stability should be assessed before any process-capability study. In many cases, process monitoring before and after a process change is required to evaluate the effect of the process change. Process monitoring alone, however, is usually not sufficient for significant process improvement. We strongly support the use of designed experiments in efforts to achieve breakthroughs in process and product performance.

We also strongly support the use of the Six Sigma define, measure, analyze, improve, and control (DMAIC) process. For a description of this approach, see Montgomery and Woodall (2008). Within the DMAIC process, process monitoring plays a large role. It is useful in the measure phase to assess current performance and to monitor the performance of measurement systems. It is also useful in the control phase to monitor input variables so that gains from the improve phase can be maintained over time. We also support the variation-reduction approaches of Steiner and MacKay (2005), which involve the collection of process data over time, but with the role of control charting downplayed.

From a practical perspective, it is important to design monitoring methods so that there are a reasonably low number of false alarms. If a scheme signals too often that a process change has occurred, but there has either been no process change or an unimportant change, then there will be a tendency for the user to ignore signals altogether. The action after a signal from a control chart can vary, depending on the field and the application. In some cases, one might simply pay more attention to the process and in others one might reset and recalibrate equipment. Many companies have out-of-control action plans that specify the actions to be taken after a signal is given.

3. Health-Related Monitoring

There are many applications of monitoring in healthcare and public-health surveillance. Woodall (2006) and Tsui et al. (2008) reviewed this area, but the number of papers and the amount of interest has increased considerably. The work in this area can be grouped into the following three broad categories: healthcare monitoring, public-health surveillance, and syndromic surveillance. We focus more on healthcare-related monitoring in our paper because this topic is expected to be of most interest to the readership. We cover the effects of aggregating data

because this practice seems more common in healthrelated applications.

Interest in health-related applications has led to a resurgence of research on monitoring with attribute data because count data are unavoidable in these applications. As an example, there have been a number of recent papers on the monitoring of a Poisson rate when the area of opportunity varies over time. Such applications are common because the size of the population at risk in a region or facility can vary over time. See, for example, Ryan and Woodall (2010), Mei et al. (2011), and Zhou et al. (2012).

3.1. Aggregation of Data

Count data are frequently aggregated, either over time, over space, or over both time and space. Burkom et al. (2004) and Dubrawski (2011) wrote on the role of data aggregation and related issues in public-health surveillance, but we believe that the effect of data aggregation on the performance of surveillance schemes deserves more study. In healthcare and safety applications, it is not unusual to see counts of adverse events aggregated over weeks, months, or even six-month periods. Because data aggregation involves a loss of information, Schuh et al. (2013) were able to show that the performance of surveillance schemes for Poisson processes suffers if data are aggregated over time. The use of the exponentially distributed time-between-event data is more effective than using Poisson-distributed data obtained after aggregation.

Reynolds and Stoumbos (2000) showed that aggregating Bernoulli data into binomial counts can slow the detection of large shifts in a proportion. In addition, Reynolds and Stoumbos (2004) gave related results for monitoring with univariate normally-distributed data.

The effect of data aggregation has been studied only for the most basic processes. Schuh et al. (2013) recommended the study of the effect of data aggregation with multivariate, multinomial, and time-series data. Study of the effect on the detection of transient process changes is also needed. Although aggregating data over time is very common, it can significantly delay the detection of process changes.

3.2. Healthcare Monitoring

There are many variables that are monitored in healthcare applications. These include the rate of hospital-acquired infections, the rate of falls by patients, and the rate of prescription errors, among many others. In many applications, the event of interest is binary, e.g., a surgical patient either survives for 30 days following an operation or does not.

An extensive amount of work has been done on monitoring the probability of an adverse event when a sequence of independent Bernoulli data is available with an assumed constant event probability when the process is in control. When the in-control probability of the event of interest is low, this is referred to in the industrial statistics literature as monitoring a "high quality process". A review of the literature on this topic was given by Szarka and Woodall (2011). Some of the methods are based on the numbers of items produced between the adverse events, leading naturally to geometric random variables. A Shewhart chart based on these geometric random variables is referred to as a g-chart.

A closely related problem is monitoring timebetween-event data under the assumption of an underlying exponential distribution. Nelson (1994) recommended transforming exponential data using a power transformation to achieve approximate normality for the in-control distribution and then using a standard individuals chart. Santiago and Smith (2013) showed, however, that this approach leads to surprisingly poor out-of-control performance in detecting decreases in the average time between events with out-of-control average run lengths (ARLs) far exceeding the in-control ARL. They recommended an alternative approach based directly on the exponential distribution.

Control charts based on the geometric and exponential distributions have not been included as part of the basic core of tools for quality practitioners, but we see this as changing. There are more and more applications where one deals with "rare events" and use of the more traditional p-chart and c-chart is ineffective. MINITAB 16, for example, now includes the g-chart and a control-chart method for time-between-event data based on the Weibull distribution, a generalization of the exponential distribution, primarily to address needs in health-related monitoring.

In healthcare, the focus is usually on monitoring the health of individual patients or the performance of physicians or hospitals. Some of the literature on the monitoring of health characteristics of individual patients with chronic health problems, such as asthma, was reviewed by Tennant et al. (2007). Thor et al. (2007), on the other hand, reviewed some of the literature on the use of control charts to improve health-care delivery.

When monitoring the performance of hospitals, physicians, or surgeons, risk adjustment is most often required to account for the varying health conditions of the patients treated. Usually, the probability of a particular adverse outcome is modeled using a logistic regression model with the independent variables reflecting the individual's health characteristics. Grigg and Farewell (2004) provided an excellent review article on risk-adjusted monitoring, but it is now out of date. Woodall et al. (2009) presented a general overview of health-related surveillance, including risk-adjusted monitoring. The level of interest and amount of work in risk-adjusted monitoring warrants another comprehensive review.

For monitoring risk-adjusted binary events, we recommend the popular cumulative sum (CUSUM) approach of Steiner et al. (2000). The authors of a number of recent papers have proposed methods that take into account the times of deaths occurring within the specified time window following surgery. See, for example, Gandy et al. (2010). These methods have been shown to be more effective but are more complicated mathematically and rely on assumptions about a survival function.

For information on the use of control charts in healthcare monitoring, we recommend the books by Winkel and Zhang (2007), which is devoted to this topic, and Faltin et al. (2012). The book by Faltin et al. (2012) contains four chapters on the subject and another chapter on the use of Six Sigma in healthcare improvement.

We strongly support the use of Six Sigma in healthcare, but find that there is currently much less of a focus on the use of metrics in healthcare than with Six Sigma in industry. We believe the use of Six Sigma in healthcare would be much more effective with an increased emphasis on the use of metrics to assess performance and the effect of improvement efforts. Simple metrics can have a huge impact. An example of such a metric is the Apgar score for the assessment of newborn infants. The heart rate, respiratory effort, muscle tone, reflex irritability, and color of the newborn are each assessed on a 0-1-2 scale and the values summed. The higher scores correspond to better physical condition. The Apgar score is used to determine the level of medical care needed. See Casey et al. (2001) for more information.

3.3. Public-Health Surveillance

In public-health surveillance one is quite often interested in monitoring disease or mortality rates. Sonesson and Bock (2003) gave an excellent review of prospective public-health surveillance, but much work has been done since. An updated review was given by Sparks (2013a). Unkel et al. (2011) provided a 30-page comprehensive review of methods for the prospective detection of outbreaks of infectious disease. Many of these methods involve or borrow from industrial SPC approaches. In addition, Tsui et al. (2011) gave a review of temporal and spatiotemporal surveillance methods for disease surveillance in public health.

In general, public-health surveillance offers more challenges than one finds with industrial monitoring. In public-health data, one frequently has to take into account day-of-week effects that one rarely sees in industrial applications. For infectious diseases, such as influenza, there are irregular seasonal effects to consider, as illustrated in Figure 1. Most often, those collecting and reporting the data are not the ones doing the analysis. This can lead to delays in obtaining data, recording and transmission errors, and to missing data. Generally, there are considerably more sources of variability in public-health data than in industrial data. In addition, other challenges with health surveillance that will be discussed in later sections include autocorrelated data, spatiotemporal monitoring, and transient 'out-of-control' conditions.



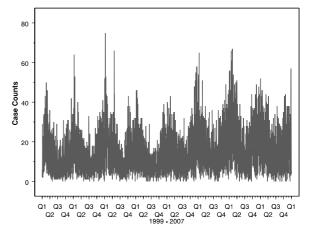


FIGURE 1. Emergency Department Arrivals, Patients with Specified Set of Symptoms, Baltimore Veterans Affairs (VA) Medical Center. (Provided by Hongzhang Zheng)

Despite the challenges, we find work in public-health surveillance very interesting. There is a focus on finding more effective algorithms for detecting outbreaks. See, for example, Tokars et al. (2009).

3.4. Syndromic Surveillance

In syndromic surveillance, data from disparate sources, including nontraditional sources, are combined to detect bioterrorism or a disease outbreak. For example, one could consider data on over-the-counter drug sales, absenteeism rates, and emergency-room visits in order to obtain an early warning of an attack or outbreak. One emphasis is using information on patient symptoms, e.g. gastrointestinal problems, instead of waiting for confirmatory laboratory diagnoses. Much of the work in this area occurred as a reaction to the 9/11 attacks in 2001. This subject could be placed in the general category of public-health surveillance, but we consider it to be a specialized topic. For a more detailed description of syndromic surveillance and the associated data, see Chapters 1 and 2 of Fricker (2013); for a description of a syndromic surveillance system, see Lombardo et al. (2003).

Some of the complications and issues involved in biosurveillance, particularly syndromic surveillance, were reviewed by Buckeridge et al. (2005), Fricker and Rolka (2006), Rolka et al. (2007), Schmueli and Burkom (2010), and Fricker (2011). A recent overview was given by Kman and Bachmann (2012). Fricker (2013) provided a comprehensive discussion of syndromic surveillance, including the detection methods currently used and an extensive list of references.

Syndromic surveillance is arguably the most challenging type of health-related surveillance. Successful research work in this area requires access to the data sources and working with a syndromic surveillance system. Generally, however, it is difficult to gain access to health-related data in the U.S.

4. Multivariate Methods

Multivariate methods are needed whenever one wants to monitor several quality variables and take advantage of any relationships among them. Bersimis et al. (2007) provided a comprehensive review of multivariate SPC methods, whereas Yeh et al. (2006) focused more narrowly on the monitoring of a variance—covariance matrix. Recent work has shown that the use of variable selection methods can improve chart performance. See, for example, Capizzi and

Masarotto (2013a). Another topic that has become important is the monitoring of contingency tables, i.e., the monitoring of multivariate categorical data. See, for example, Li et al. (2012) and Yashchin (2012). Spatiotemporal surveillance, multistage monitoring, multiple stream monitoring, and profile monitoring, all discussed below, are other examples of multivariate monitoring.

4.1. Spatiotemporal Surveillance

Spatiotemporal data consist of counts of events over time, but each event is associated with a location in a region of interest. Sometimes the exact location is known, but most often one only knows in which of several subregions the events are located. Most of the work on prospective spatiotemporal monitoring has been done in public-health cluster-detection applications, where the goal is to detect emerging clusters where disease rates are higher than expected. See, for example, the books by Lawson and Kleinman (2005) and Rogerson and Yamada (2009) and the review paper by Robertson et al. (2010).

The scan method of Kulldorff (2001) is widely used with freely available software available at www .satscan.org/. With the spatial scan method, a circle, or some other shape, is moved around the region of interest and the observed count is compared with the expected count. The size of the circle is allowed to vary. If the observed count is significantly higher than the expected count, then a cluster is flagged. The spatiotemporal method works similarly except that the circles are extended back in time to form cylinders. Sonesson (2007) gave an excellent discussion of this approach, relating it to the CUSUM likelihoodratio method. Woodall et al. (2008) argued that further study of Kulldorff's (2001) spatiotemporal scan method is warranted. Several types of likelihoodratio-based generalizations of the scan method were given by Tsui et al. (2012).

Data are often collected on products using laser scanners and coordinate measurement machines. Thus, numerous measurements are available on each item at various locations. Some of the issues in monitoring with these types of data were discussed by Wells et al. (2012, 2013). It can be very helpful to use engineering knowledge to better monitor and find root causes of changes in variation patterns. Apley and Lee (2010) discussed some of the issues involved with this type of approach and provided some useful references.

A related area is the use of images for process

monitoring. Most often, images have been used in industry for product inspection, where nonconforming items are separated from the conforming items, but we see opportunities for detecting more subtle quality changes before nonconforming items are produced. Megahed et al. (2011) reviewed work on the use of control charts with image data. Image monitoring falls into the area of spatiotemporal surveillance because images are taken over time and any product faults appear as spatial features on the images. Megahed et al. (2013) applied spatiotemporal methods to the analysis of image data. Generally speaking, the use of control charts with image data is not yet well-developed. We encourage researchers to investigate applications in this area.

The area of prospective spatiotemporal surveillance is a challenging, but very important, area of research. Historically, the data used in SPC has been strictly temporal in nature with no spatial component considered. Thus, most work in this area is recent.

4.2. Profile Monitoring

In an increasing number of industrial applications, the quality of a process or product is best described by a function, called a "profile". In these applications, a response variable is related to one or more explanatory variables. In these cases, changes in the profile over time are of interest. Various types of models have been used to represent profiles, including simple linear regression, nonlinear regression, multiple regression, nonparametric regression, mixed models, and wavelet models.

An example of a profile is shown in Figure 2. This figure shows the force vs. the position of the tool in a broaching process in a manufacturing application. Broaching is a machining process that uses a toothed tool, called a broach, to remove material. Each application of the broaching process yields a profile and changes in the profile shape over time can indicate wear or other problems with the tool.

If the profile can be represented by a parametric model, then typically one monitors the parameters of the model with separate control charts, provided the parameter estimators are independent, or monitors the parameters jointly with a multivariate control chart. In quite a few cases, the profile shape cannot be adequately represented by a parametric model, so a nonparametric approach is required. See, e.g., Qiu et al. (2010) and Zou et al. (2008). Sometimes it is useful and simpler to monitor some fea-

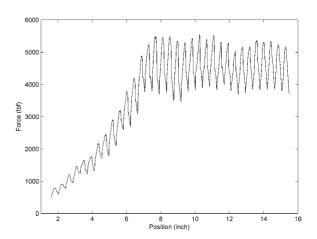


FIGURE 2. An Example of Profile Data from a Broaching Process. (Provided by Jaime A. Camelio of Virginia Tech)

tures of the profile, such as the maximum value. Profile monitoring now includes the monitoring of two-dimensional shapes and three-dimensional surfaces. Effective monitoring in practical applications requires subject matter expertise and a focus on root cause analysis.

We recommend the discussion given by Chipman et al. (2010), who gave a very practical perspective and mentioned several topics needing further investigation. These topics included profile monitoring with subgroups containing more than one profile, dealing with autocorrelation across profiles (see Paynabar et al. (2013)), and the use of covariate information. There is also work needed on the effect of estimation error on the Phase II performance of profilemonitoring methods. Mahmoud (2012) and Aly et al. (2013) have provided the only work thus far on this topic.

Reviews of work in profile monitoring were given by Woodall et al. (2004) and Woodall (2007), but for a more up-to-date overview, we recommend Noorossana et al. (2011). The chapters in this book were written by some of the leading researchers in profile monitoring.

4.3. Multistage Monitoring

Even the simplest manufacturing processes are comprised of several production steps. In many industrial applications, one needs to take into account these multiple process steps and model the effect of one process step on the next. If one monitors only

the output of a subprocess without taking into account the input, then incorrect conclusions can be reached. The use of multistage data also enables one to understand variation transmission through a process, referred to as stream-of-variation analysis. Research in this area of surveillance was reviewed in the book by Shi (2006) and in the papers by Tsung et al. (2008), Shi and Zhou (2009), and Liu (2010).

The key ideas of multistage monitoring are useful and important, but implementation in practice often requires the development of a customized approach that depends on the manufacturing setup and the available data. In our experience, the data from the various stages of manufacturing processes are frequently not integrated in such a way that analysis is easily done.

5. Autocorrelated Data

As data are collected more closely in time or space, the observations are more likely to be autocorrelated. Knoth and Schmid (2004), Psarakis and Papaleonida (2007), and Prajapati and Singh (2012) reviewed the extensive literature on process monitoring with autocorrelated data. Autocorrelated data show up in profile-monitoring applications and in publichealth surveillance. One interesting development in this area is the monitoring of autocorrelated count data. See, for example, Weiß and Testik (2009) and Mousavi and Reynolds (2009).

The study of univariate autocorrelated data has possibly reached the point of diminishing returns, but relatively little work has been done on the more challenging problem of monitoring multivariate autocorrelated, and possibly cross-correlated, data. The review of multivariate SPC by Bersimis et al. (2007) has a section on this topic. There is some recent work by Jarrett and Pan (2007) and Cheng et al. (2013). This topic is related to the monitoring of many data streams discussed in Section 7.

The topic of forecasting is closely related to the topic of process adjustment. A review of statistical process adjustment was provided by del Castillo (2002, 2006). Many, including Box et al. (2009), have recommended using control charts in conjunction with control algorithms. Some relevant references were also given by del Castillo (2006).

Much of the research in monitoring with autocorrelated data is based on the assumption of a known time-series model. Ledolter and Bisgaard (2011),

however, discussed some of the practical issues related to fitting time-series models to process data.

6. Effect of Estimation Error

The vast majority of the work on designing and determining the properties of control charts for the on-going monitoring in Phase II is based on the assumption that the in-control parameter values are known. In practice, however, the in-control parameter values must be estimated from a Phase I dataset. Jensen et al. (2006) and Psarakis et al. (2013) provided reviews of the literature on the effect of the estimation error on control-chart monitoring performance in Phase II. The overall conclusion is that more data are needed than one might expect in order to have performance reasonably close to that when the in-control parameters are assumed to be known. Zhang et al. (2013) showed that the needed Phase I sample sizes can be prohibitively large when monitoring with time-between-event data when the event of interest is rare.

Woodall and Montgomery (1999) mentioned that more research was needed in this area. Much work has been done, but more is needed on this important practical area. In particular, there is a need for the further study of the effect of estimation error on risk-adjusted methods with Jones and Steiner (2012) having done the only work on this topic.

7. Monitoring Many Process Streams

In Woodall and Montgomery (1999), the authors wrote that process data can be available every second or every few minutes on hundreds of process variables or product characteristics. Over the last 10 years, the number of variables available in many process-monitoring applications has grown tremendously. Such data streams are sometimes referred to as being "high dimensional". The amount of data available for process monitoring continues to grow, as discussed by Megahed and Jones-Farmer (2013).

The work done on "multiple stream processes" in SPC has most often been based on the assumption of independence within and between data streams. Methods tended to be based on detecting changes in a single stream or a simultaneous shift in all streams. Epprecht and Simöes (2013) gave a review of the more traditional methods for monitoring multiple stream processes. High-dimensional data monitoring can be complicated, however, by autocorrelation and seasonal effects within the data streams and correla-

tion across streams. Process disturbances can affect a single stream or several streams. Due to the complications and computational issues, there is much work to be done in this area of application.

With respect to computer network surveillance, De Oca et al. (2010) reported that, even in small networks, the number of monitored variables can be in the hundreds and that network monitoring can lead to massive computational problems. Marvasti (2012) mentioned some cloud computing applications in which there could be a million input data streams with observations taken on each stream every 5 minutes. For other work on network surveillance, we recommend the papers by Denby et al. (2007), Lambert and Liu (2006), and Jeske et al. (2009).

In a healthcare application, Spiegelhalter et al. (2012) considered the problem of simultaneously monitoring 200,000 indicators of excess mortality in the UK health system. Other high-dimensional applications include the monitoring of sensor data and the monitoring of social networks (McCulloh and Carley (2008), McCulloh et al. (2012), Sparks (2013b)). In many of these applications, only increases in the monitored variables are of interest.

With thousands of input data streams, one will likely have out-of-control signals at each time period for which data are collected. Thus, typical metrics like the probability of a false alarm and ARL lose their usefulness. Under a false discovery rate (FDR) approach, one controls the percentage of signals that are false alarms. There have been some recent articles of the use of the FDR with control charts, including Grigg and Spiegelhalter (2008), Li and Tsung (2009), and Spiegelhalter et al. (2012). We find the use of the FDR metric appealing, but believe further study of these approaches is warranted.

The FDR methods require one to convert controlchart statistics to p-values and then to analyze the pvalues. Benjamini and Kling (1999) initially proposed the idea of using p-values with control charting while Grigg and Spiegelhalter (2008) showed how to obtain such p-values for a CUSUM chart. Lambert and Liu (2006) also took a p-value-related approach. Li et al. (2013) more recently discussed using p-values in control charting.

The classical multivariate monitoring procedures are typically used to detect changes in the process mean vector or covariance matrix. These traditional techniques, however, can be overwhelmed by the problems that are typically encountered in monitoring many of the real-time data streams that are frequently encountered today. This includes data from manufacturing environments, but also financial data such as credit scores or financial transactions, computer systems intrusion and security applications, and environmental data. Because of the increased rate and amount of data obtained, Bisgaard (2012) stated, "These developments (in obtaining data) will necessitate the increased use of multivariate statistical techniques such as Hotelling's T^2 , principalcomponents analysis, partial least squares, discriminant analysis, multivariate regression, factor analysis, canonical correlation, and multivariate timeseries analysis. The data are often very high dimensional, which can be a challenge to the scalability of these traditional multivariate monitoring methods. For some approaches to this problem, see Mei (2010), Ross et al. (2011), Zou and Qiu (2009), Zou et al. (2011), Zou et al. (2012), and Wang and Jiang (2009).

Other issues not handled well within the traditional multivariate process monitoring framework include nonlinear relationships among the monitored variables, nonnormal distributions, categorical data, mixtures of categorical and continuous data, and missing data, to name a few. Discussion of these problems and some recent potential directions for solutions were described by Ding et al. (2006), Stoumbos and Sullivan (2002), Laungrungrong et al. (2011), and Imtiaz and Shah (2008). More research in these areas is certainly needed.

Monitoring with high-dimensional data will require new approaches. A recent paper by Deng et al. (2012), for example, utilized an approach they call real-time contrasts between reference (in-control) data and current or real-time data, and converts the problem of assigning samples from the real-time data into a dynamic classification problem. The generalized likelihood-ratio principle is used to construct control statistics and the classifier is based on a standard supervised learning technique, random forests. This is a promising approach that can be applied to a wide variety of nontraditional multivariate monitoring problems.

8. Nonparametric Methods

In Woodall and Montgomery (1999), the authors anticipated an increasing role for nonparametric monitoring methods. For a review of nonparametric control-charting methods proposed as alternatives to the basic univariate and multivariate parametric

charts, the reader is referred to Chakraborti et al. (2001), Chakraborti et al. (2011), and Chakraborti (2011). Many of the nonparametric methods are rank based. Nonparametric regression methods are used in profile monitoring.

Despite their advantages in reducing the distributional assumptions required to design control charts with specified in-control performance, it does not seem that nonparametric methods are gaining a foothold with practitioners. This could be partially due to a lack of statistical software for implementing the methods, a lack of familiarity, and a lack of textbook coverage. Nevertheless, this research area remains active. See, for example, Qiu and Li (2011) and Zou and Tsung (2011).

9. Generalized Likelihood Ratio and Change-Point Methods

There have been a series of papers proposing methods based on the generalized likelihood ratio (GLR) approach. The well-known CUSUM method is equivalent to using a change-point method and maximizing a likelihood-ratio statistic over all possible shift locations. For the CUSUM method, the size of the out-of-control shift in the parameter that is of interest to be detected quickly must be specified. The basic GLR approach generalizes the CUSUM approach by also maximizing the likelihood ratio over all possible shift sizes in the underlying parameter.

The statistical performance of the GLR methods is typically better overall than that of the CUSUM chart over the range of possible shift sizes. In addition, the control limit is the only design constant that needs to be determined based on a specified incontrol ARL. For more information on GLR-based surveillance methods, we recommend Apley and Shi (1999), Capizzi (2001), Reynolds and Lu (2010), and Capizzi and Masarotto (2012).

The related "adaptive control charts" represent a competing approach in which the design parameters of the chart, the sample size, and/or the sampling interval are adjusted depending on the observed data. Tsung and Wang (2010) and Epprecht et al. (2003) provided reviews of adaptive control charting.

The GLR approach is related to change-point detection because an estimate of the time of any process shift is provided as part of the analysis. Generally, there has been a considerable amount of research on combining change-point detection with process

monitoring. Change-point methods are used in three ways. With each sample in Phase II, one can run a change-point method on all or some of the past data. Hawkins et al. (2003) provided an introduction to this approach and it was also used by Zou et al. (2006). Change-point methods are frequently applied in a single analysis of the Phase I data, an approach taken by Mahmoud et al. (2007). Finally, sometimes change-point methods are used after a control-chart signal in an effort to determine when the process changed. See, for example, Pignatiello and Samuel (2001) and the review papers by Amiri and Allahyari (2011) and Atashgar (2013).

10. Bayesian Methods

Quite a few Bayesian methods have been proposed for process monitoring, Apley (2012), for example, proposed a Bayesian method for monitoring the mean of a process. His reference list includes a number of Bayesian surveillance methods. Pan and Rigdon (2012) and Tan and Shi (2012) recently proposed Bayesian methods for multivariate quality control. In addition, Zeng and Zhou (2011) proposed a Bayesian method for risk-adjusted monitoring.

The Shiryaev-Roberts surveillance method (Shiryaev (1963), Roberts (1966)) has a quasi-Bayesian justification. This approach and its optimality properties have received considerable attention in the more mathematical statistics literature. See, for example, Tartakovsky and Veeravalli (2004), Mei (2006), Siegmund and Yakir (2008), and Polunchenko and Tartakovsky (2010). We have seen very little use of the Shiryaev–Roberts method in quality-control applications, however, likely because the CUSUM statistics and plots are much more intuitive. Kenett and Zacks (1998) covered the method, but most statistical quality-control textbooks do not. Mahmoud et al. (2008) presented a comparison of the Shiryaev-Roberts method with the CUSUM method when monitoring the mean of a normal distribution.

We believe that a review of Bayesian approaches to surveillance would be very useful. These methods do not seem widely used, which is somewhat odd considering the success of Bayesian methods in other areas of applied statistics. Disadvantages of Bayesian methods include an added layer of complexity and the amount of computation required. A discussion of the general framework, advantages, disadvantages, and limitations of Bayesian surveillance approaches, however, could be very interesting and informative.

11. Phase I Methods

The vast majority of research on process monitoring has been on Phase II performance. Phase I, however, can be even more important because much can be learned about process performance. It could be that no Phase II monitoring is required after the insights and improvement obtained during Phase I. The collection of historical observational data is also a key component of the process-variation reduction detective work advocated by Steiner and MacKay (2005).

The use of baseline data from Phase I is required for all process-monitoring procedures other than "self-starting" methods, which require only a few data points. Capizzi and Masarotto (2010) provided an example of a self-starting chart. Self-starting charts are not a replacement for Phase I analysis. These methods would be useful in situations for which one has little historical data and observations arrive quite slowly. A review of self-starting methods, along with a discussion of their proper use, is needed.

Important Phase I statistical tools include graphical methods such as the multi-vari chart, outlier-detection methods, change-point methods, the selection of the in-control model, and the robust estimation of in-control process parameters. The selection of quality characteristics and the effective design of the sampling or inspection plans, sometimes referred to as "rational subgrouping", plays a key role.

Chakraborti et al. (2009) gave an overview of some Phase I issues and methods, primarily focusing on the use of univariate data under the assumption of independence of observations over time. There are dozens of papers on Phase I methods. Paynabar et al. (2012), for example, did an excellent job in studying Phase I data for risk-adjusted monitoring. Jones-Farmer et al. (2013) provided a more recent overview of Phase I issues and methods.

12. Performance Metrics

The choice of performance metric can have a large effect on the choice of monitoring scheme. The distinction between active and passive surveillance is important because it affects which performance metrics are most relevant in a particular application. Industrial surveillance tends to be active in the sense that corrective action can be taken once a signal is given, with a more or less immediate impact, whereas public-health surveillance tends to be passive.

Many more performance metrics have been proposed for use in health-related surveillance than for use in industrial surveillance. One reason for this is that sometimes the surveillance statistic is not reset to its initial value after a signal of an outbreak in public-health surveillance. Another reason is that public-health outbreaks are often temporary, whereas, in industrial applications, one typically assumes that any process shift or change is sustained. For temporary outbreaks, ARL performance is not meaningful and one is interested in the probability of detecting the outbreak or how quickly the outbreak is detected given that it is detected. In addition, in some cases, one wants to consider a finite monitoring time. In this case, it is more reasonable to control the probability of a false alarm within this timeframe. See, for example, Gombay et al. (2011).

Frisén (2007), Fraker et al. (2008), Kenett and Pollak (2012), and Fricker (2013, Chapter 6) reviewed many of the various performance metrics, along with some of their advantages and disadvantages. Woodall and Ryan (2013) discussed several performance metrics that can be informative when monitoring with rare event data. In these applications, the time between plotted points on a chart varies and the ARL metric may need to be supplemented with the average time to signal (ATS) metric or the average number of observations to signal (ANOS) metric.

Our preference for industrial applications with sustained shifts is to consider zero-state, steady-state, and worst-case run-length performance. In many cases, convergence to steady-state conditions is relatively quick. There are methods that have good zero-state performance, but poor steady-state performance, due to an implicit head-start feature.

Some limitations of the use of the ARL metric were discussed by Mei (2008), who reviewed much of the literature on the more mathematical approaches to surveillance. He showed that the use of the ARL metric is not reasonable in some cases when the observations are dependent. His arguments, however, do not seem to apply to standard SPC practice. The ARL metric, however, can be misleading, as illustrated by Zhou et al. (2012). Some researchers prefer to consider percentiles of the run-length distribution. As mentioned in Section 7, the FDR metric may be more useful than the ARL metric in high-dimensional monitoring.

Some researchers, such as Frisén (2006), prefer metrics that require one to specify the distribution

of the time at which the process change occurs. Because this distribution will be unknown in practice, it seems useful to look at a range of such distributions. If so, then one moves more toward the zero-state and steady-state cases.

New methods can require the use of new performance metrics. As mentioned in Section 7, the FDR metric has advantages over the ARL metric in high-dimensional monitoring. In spatiotemporal surveillance, one requires metrics that measure how well methods identify the cluster area. See, e.g., Buckeridge et al. (2005) and Megahed et al. (2013).

Finally, it is important to be able to design monitoring shemes with specified in-control performance and to assess out-of-control performance. This can be done numerically (Knoth (2012) and Li et al. (2013)) or using computer simulation (Capizzi and Masarotto (2013b)).

13. More Specialized Topics

In this section, we give a variety of research and application areas in process monitoring for which there are review papers available or needed.

13.1. Monitoring Rare Events

In an increasing number of applications, practitioners are interested in the monitoring of rare events. Examples include the monitoring of nonconforming manufactured items with high-quality processes, congenital malformations, and industrial accidents. The methods based on the geometric and exponential methods discussed in Section 3.2 are applicable. A review of recent work was provided by Woodall and Ryan (2013).

The monitoring of rare events is an important, yet very challenging, problem. No current method works well. The power to detect process changes is low and the Phase I sample sizes required for parameter estimation can be prohibitively large. We agree with Steiner and MacKay (2004) that it is important to identify a continuous variable to monitor, if possible, instead of a Bernoulli variable representing the occurrence or nonoccurrence of the event of interest.

${\bf 13.2.} \ \, {\bf Multinomial} \ \, {\bf and} \ \, {\bf Multiattribute} \\ \, {\bf Methods} \\$

In some monitoring applications, there may be several categories in which items are placed, not just two, resulting in more information about the process. Topalidou and Psarakis (2009) gave an extensive review of papers on this topic and other applications

where there are several categories or several attribute quantities of interest. Jahromi et al. (2012) gave a review of charts based on fuzzy logic that can be applied when there are multiple categories, but we do not advocate the use of fuzzy methods.

13.3. Monitoring with Reliability Data

There is an increasing emphasis on monitoring reliability, life-test, and warranty data. Reliability data are often censored and lifetimes are often modeled using a Weibull distribution. See Yashchin (2010), Olteanu (2010), Pascual and Li (2012), and Lawless et al. (2012) for some recent work done on these topics. A review paper on the monitoring of reliability data would be very useful. We see this research area as having considerable potential.

13.4. Use of Single Control Charts

Some researchers see advantages in using a single control chart when monitoring a process characterized by more than one parameter. One can sometimes more easily control the in-control performance with this approach and then rely on diagnostics to identify the parameter change that caused a signal. See Cheng and Thaga (2006) and McCracken and Chakraborti (2013) for reviews of these types of methods.

13.5. Neural Networks

For those interested, Zorriassatine and Tannock (1998) and then Psarakis (2011) reviewed the use of neural networks in statistical process control. One of the primary applications is for control-chart pattern identification. Despite the large number of papers on this topic, we have not seen much practical impact on SPC.

14. Conclusions

The importance of process monitoring applications continues to grow. Generally, many of the developments in process monitoring are being driven by the access to more and more data. We encourage further research in this area. In particular, work is needed on developing strategies to deal with the monitoring of a large number of data streams. Additional methods are also needed for visualizing results when there is a large number of data streams or a large amount of spatiotemporal data. We believe that the use of image monitoring and spatiotemporal surveillance will become more common. We expect risk-adjusted monitoring to become increasingly im-

portant due to the necessity of improving healthcare performance. Finally, we encourage research on the effect of aggregation of data on the performance of surveillance methods.

Acknowledgments

The authors gratefully acknowledge the helpful comments by the Editor; an anonymous referee; Dan Apley, Northwestern University; Giovanna Capizzi, University of Padua; Subha Chakraborti, University of Alabama; Ronald D. Fricker, Jr., Naval Postgraduate School; Daniel R. Jeske, University of California—Riverside; Guido Masarotto, University of Padua; Stelios Psarakis, Athens University of Economics and Business; Wolfgang Schmid, Europa-Universitaet Viadrina; and the following Virginia Tech graduate students: Rebecca Dickinson, Gregory Purdy, Sarah Richards, Mohammed S. Shafae, Hongyue Sun, Wenmeng Tian, and Xiang Zhang. Any errors and omissions, however, remain the responsibility of the authors.

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