**Chapter 8**

**Time to Adverse Events**

# [H1] Learning Objectives

1. Calculate days to sentinel events
2. Calculate daily probability of rare adverse events
3. Create time-between control charts

# [H1] Key Concepts

* Sentinel events
* Average daily probability of rare events
* Time to event
* Time between events
* Time-between control charts

# [H1] Chapter at a Glance

This chapter focuses on constructing a control chart for the time between adverse sentinel events (e.g., wrong-side surgery, excessive delays in the emergency room boarding, medication errors). The analysis of sentinel adverse events is marked by a paucity of data. These events are rare. The method of analyzing these data must assume that there are few occurrences. The sample size may be large, but in most cases the adverse event does not happen. One way to overcome this difficulty is to analyze time between events. Such an analysis is different from analysis of rates of occurrences, which in sentinel events is very low.

# [H1] Distribution of Sentinel Events

In 2002, scholar Louis Anthony Cox, Jr., provided a thorough explanation of risk analysis using binary data (Cox 2002). This chapter relies on Cox’s description and shows how they apply to analysis of the risk of sentinel events. We begin with distribution of adverse events, a concept introduced earlier but explained again in the context of rare events.

A probability density function gives the frequency of occurrence of events at a particular time. In contrast, a cumulative probability distribution function gives the probability of events occurring prior to a particular time. Take a look at exhibit 8.1. For each day, the number of medication errors is divided by the number of patients to see what the daily probability of medication errors is. The data were collected over a year, but for simplicity, we have collapsed days 4 through 365 into one category. The first column shows the days, and the second column shows the probability density function. At each value, it provides the probability of the event listed. For example, 1 percent of medication errors occur in day 1 of a hospitalization (or the probability of medication error in day 1 is 0.01), 6 percent occur in day 2, 4 percent occur in day 3, and the remainder of the errors occurs in days 4 through 365. The cumulative distribution function is also given in the third column. It starts at 0.1 percent and increases or stays the same thereafter. Note that it never decreases. The cumulative distribution function gives probability of occurrence of medication error on a date and prior to that date. For example, 7 percent of medication errors occur on the second day or prior to it. The cumulative distribution function changes in steps that are equal to the probability of the event in the last period. For example, the increase in the cumulative distribution function by going from day 1 to day 2 is 6 percent, which is equal to the probability density function associated with day 2.

**Exhibit 8.1** Density and Cumulative Distributions

|  |  |  |
| --- | --- | --- |
| **Day** | **Probability Density Function** | **Cumulative Distribution Function** |
| 1 | 0.01 | 0.01 |
| 2 | 0.06 | 0.07 |
| 3 | 0.04 | 0.11 |
| 4–365 | 0.89 | 1 |

**[H2] Expected Value**

Knowing the probability density function is a very important step in deciding what to expect. It is the building block on which the rest of the analysis rests. The expected value of a distribution (*E*) is calculated by multiplying the probability of the event by its value and summing across all possible values of the event:

In this equation, *X* is a random variable marking a day in our data when sentinel events occurred, *i* marks a particular day, *E*(*X*) is the expected value for the event *X*, and *p*(*X = i*) is the probability of event *x* occurring on day *i*.

Using the data in exhibit 8.1, to calculate the expected value, we first multiply the value of each day by the probability of the event occurring on that day (this gives the third column in exhibit 8.2). In the first row of exhibit 8.2, probability of medication errors is multiplied by 1 chance to obtain 0.01. In the second row, 6 percent is multiplied by 2 to obtain 0.12, and so on. The expected day of medication error is the sum of the products in third column. In this example, it is 164th day. Therefore, the most likely day to expect a medication error is on day 164.

**Exhibit 8.2** Expected Days for Medication Errors

|  |  |  |
| --- | --- | --- |
| **Day** | **Probability Density Function** | **Day × Probability** |
| 1 | 0.01 | 0.01 |
| 2 | 0.06 | 0.12 |
| 3 | 0.04 | 0.12 |
| 184 | 0.89 | 164 |
| Expected Days | | 164 |

**[H2] Bernoulli Distribution Revisited**

A full specification of the probability for every day may be onerous. A simpler way to estimate a probability density function is to assume a general shape for the probability function and use a handful of data to estimate the parameters of the function. A great deal of thought has gone into recognizing different probability density functions. The most common probability density functions for discrete variables are Bernoulli, binomial, geometric, and Poisson functions. This chapter describes each of these functions and explains the relationships among them. If our focus remains on events that either happen or do not happen, then these four density functions are sufficient to describe many aspects of these events.

Many events have Bernoulli distributions. For example, wrong-side surgery has a Bernoulli distribution. Similarly, incorrect blood transfusion, medication errors, fires in the operating room, and many other sentinel events have a Bernoulli distribution. In a Bernoulli density function one assumes that two outcomes are possible. Either the event occurs or it does not. In other words, the events of interest are mutually exclusive. Bernoulli function also assumes that the possible outcomes are exhaustive, meaning that at least one of the two events must occur. In a Bernoulli density function, the event occurs with a constant probability of *p*. The complement event occurs at probability of 1 – *p*:

By the phrase “constant probability *p*,” we mean that this frequency is not likely to change. The frequency changes if the underlying process that generated the event changes. For example, the probability of medication error on any particular visit may be assumed to be *p*, and this probability may be assumed to be constant from visit to visit if the underlying care processes have not changed. Typically, it is assumed that the probability is calculated for a specific number of trials or a specific period. For example, a nursing home facility over a year’s time may have a 5 percent chance per day of a patient escaping the premises. This daily probability can be calculated by examining time between events, e.g. by examining time between two patients escaping. We will return to these calculations in the next section.

The Bernoulli assumption of mutually exclusive and exhaustive events is not always met. At first glance, it may seem that a patient is either alive or dead and, therefore, this variable meets the definition of Bernoulli function. On closer examination, we may find patients whose brains are dead but they are kept alive. Such examples contradict the assumption of mutually exclusive and exhaustive events. Sometimes, the assumptions of absence or presence of a sentinel event are accepted even though the event has different degrees of presence.

**[H2] Geometric Distribution**

Time to a repeated, independent, Bernoulli events has a geometric distribution. Think of a situation in which a Bernoulli event is repeatedly tried. For example, every day and in every visit, there is a chance that a medication error might occur; this is a repeated occurrence of a Bernoulli trial. For another example, in every surgery, there is a chance that fire may break out. In this sense, fire in operating room is either present or absent and can be thought of as repeated Bernoulli trials. These examples show repeated Bernoulli events.

Assume further that in these trials, the probability of occurrence of the event is not affected by its past occurrence—in other words that each trial is independent of all others. This assumption makes sense if, after one sentinel event, we do not change the process to reduce the probability of future events. There are several situations where the assumption of independent repeated trials does not make sense. For example, probability of contagious infection changes if there was an infection in the prior day. Therefore, independent trials cannot be assumed in this situation. But in many situations it can and when we can make this assumption, there is a lot we can tell about the probability function under this assumption.

If an event has a Bernoulli density function, then time to the event—that is, time to the next occurrence of the event—has a geometric distribution. One repeats the independent trials until the event occurs. The geometric density function is given by multiplying probability of one occurrence of the event by probability of *k* − 1 non-occurrences that should precede it:

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## [H3] Example: Elopement

In this example, we have three repeated trials for tracking patients’ elopement over time (see exhibit 8.3).We are assuming that the probability of elopement does not change if one patient has eloped in the prior days (in other words, patients do not learn from each other’s elopement). On day 1, the patient may elope or not. On day 2, the same event may repeat and another patient may elope. The process continues until day 3. As you can see, the patient may elope on different days, and on each day, this probability of elopement is constant and equal to values on prior days. The geometric density function gives the probability of the first elopement occurring on *k*th day. For that to occur on *k* − 1 occasions, there should have been no elopement. The first part of the function calculates the joint probability of no elopement in *k* − 1 occasions; if we assume each day is independent, then this is the probability of no elopement, 1 − *p*, repeated *k* − 1 times. The last part of the equation calculates the probability of elopement on the *k*thoccasion, which is simply *P*.

**Exhibit 8.3** Repeated Three Trials for Elopement of Patients



**[H1] Days to Event**

Geometric distribution is important because it helps us predict how many days will pass before an adverse event will occur. In fact, the calculation of the expected number of days before an event occurs is quite simple: It is 1 divided by the probability of the occurrence of the event in every trial, written as

, or

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Geometric distribution can be used to estimate the probability of rare events. We can observe a process until the event occurs. Given that the event is rare, we may observe the process for a long time, but when the event does happen, we can produce a quick estimate of its daily probability (Alemi 2007).

**[H2]: Example in Wrong Side Surgery**

For example, suppose today an individual had a wrong-side surgery; but there is no history of wrong side surgery for any other patient in the last 10 years. If an event has occurred once in the last decade, then 3,649 days passed before the event has occurred. Then, the daily probability of the event is 1/3649, which is a very small probability indeed. Despite the fact that this probability is very small, we are confident about its accuracy because we have not observed the event more than once in 3650 days of observations. We have plenty of observations but only one case in which the wrong-side surgery has occurred. The assumption of Bernoulli distribution and repeated trials of daily Bernoulli events allows us to estimate days until the first occurrence of wrong-side surgery as a geometric density function.

## [H2] Example in Privacy Violations

For another example, suppose we want to understand how privacy violations are occurring in our facility. All we have is date of incidents. From these dates, we can calculate the daily probability of various privacy violations, assuming a geometric distribution. Suppose the data show that incidents of disgruntled employees selling information had occurred on May 11, 2010, and November 22, 2013, creating 1,290 days until the next occurrence of this event. The dates of incidents of a clinician discussing patient information in a social gathering were December 5, 2015, and December 26, 2016, with 387 days between events. Taken as a whole, privacy violations happened on May 11, 2010; November 22, 2013; December 27, 2015; December 5, 2016; November 22, 2016; and December 27, 2016. There were 938 days between the first two dates, 352 days between the next two dates, and 35 days between the last two dates. On average, the next privacy violation occurs in (938+352+35) ÷ 3=442 days. The daily probability of privacy violation is 1/442 = 0.0023. As seen in this analysis, geometric distribution allows us to easily quantify the daily probability of various events. We can conclude that the sale of information is rare, while privacy violation in social gatherings is more common. These statistics can help set priorities for where the organization should focus its prevention efforts.

# [H1] Time-Between Charts

Managers are often concerned about whether improvement teams have effectively reduced incidences of adverse events. Because times to these events have a geometric distribution, a specific kind of control chart, called a *time-between control chart*, has been designed to analyze these data. There are many more ways to construct a control chart, but the specific time-between charts are best used when the following four assumptions are met:

1. Data has been collected over time with one observation per period.

2. The chart should be drawn for dichotomous, discrete rare events. For example, time-between charts can be constructed for days on which the requirements of a special diet were not met, days without exercise, days without coffee, days without junk food, days until an unsatisfied customer submits a complaint, days to the next adverse event, days until suicide, days to wrong-side surgery, days without smoking, and so on.

(3) Observations over time should be independent of each other. Knowing the value of an observation during one period should not change the probability of observation at the next period.

(4) The time to the event should have a geometric distribution, in which a long wait for the event is increasingly rare.

**Exhibit 8.4** Use the Right Chart in the Right Setting

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Are Observations Independent of Each Other?** | **Number of Observations per time Period** | **Scale on which Observation Was Measured** | **Outliers Present?** | **Recommended Chart** |
| No | - | - | - | None |
| Yes | One | Interval (continuous) | Yes | Tukey |
| Yes | One | Interval (continuous) | No | Tukey, XmR |
| Yes | One | Binary or discrete | Yes, by definition rare event | Time-between |
| Yes | Multiple | Interval (continuous) | No | X-bar  or risk-adjusted X-bar |
| Yes | Multiple | Binary or discrete | No | P-chart  or risk-adjusted P-chart |

There are many other types of control charts besides time-between charts. You could use a p-chart when tracking mortality or common health events over time. A p-chart is reasonable only if the event of interest is not rare. You could use an X-bar chart for tracking health status and satisfaction of a group of patients over time. You could use an XmR or Tukey chart to track data from one patient over time. Exhibit 8.4 helps you decide which chart is appropriate for your application. Also keep in mind that all control charts can and should be case-mix/risk adjusted. For these situations, risk-adjusted versions of the control chart should be used.

**[H2] Step 1**: **Verify that the Event Is Rare**

There are four steps in the process of constructing control limits for a time-between chart. We describe these steps in the context of the assessment of patient complaints. In time between charts, control limits must be derived for rare events. If positive comments are more common, it is important to plot days to positive comments. If complaints are relatively rare, plot days to complaints.

To verify that the event is rare, calculate *R* as the ratio of the number of events to frequency of the opposite event. For example, the ratio of complaints to positive comments. If positive comments are relatively rare, calculate *R* as the ratio of positive comments to complaints. *R* must always be less than 1. If the data distinguish between pre- and post-intervention periods, the value of *R* is calculated from either pre- or post-intervention data but not from all of the data. The period used for calculation of *R* is selected so that it would minimize the value of *R*. If the pre-intervention period has little variation in the duration of the event being tracked, *R* is calculated from the pre-intervention period. Otherwise, it is calculated from the post-intervention period. Then, comparing the observed data to the control limits allows us to examine the impact of the intervention.

**[H2] Step 2: Calculate Consecutive Time-Between Events**

Consecutive days between events are calculated based on what happened on the previous day and today. Exhibit 8.5 shows how these values are calculated for complaints. The analysis either plots consecutive complaints or consecutive positive comments, based on which one happens less often. If complaints are less frequent, the chart is constructed by plotting consecutive complaints on the *y*-axis and time since start on the *x*-axis. If otherwise, the control chart is constructed by calculating the consecutive instances of praise.

**Exhibit 8.5** Rules for Calculating Length of Time between Missed Days

|  |  |  |  |
| --- | --- | --- | --- |
| **Yesterday** | **Today** | **Days to Complaint** | **Days to Positive Comments** |
| No data | Complaint | 1 | 0 |
| No data | Positive Comment | 0 | 1 |
| Complaint | Positive Comment | 0 | 1 + yesterday's score |
| Complaint | Positive Comment | 0 | 1 |
| Positive Comment | Complaint | 1 | 0 |
| Complaint | Complaint | 1 + yesterday’s score | 0 |
|  | | | |

**[H2] Step 3: Calculate Control Limit**

Calculate upper control limit (UCL) as *R* plus 3 multiplied by the square root of R multiplied by 1 plus R, which looks like:

For example, if complaints are occurring once in 20 comments (R = 0.05), then the UCL is

There is no lower control limit (LCL) for time-between charts. As the event plotted is rare, the LCL will always be a negative number. Given that time cannot be negative, the LCL does not make sense in the context of time-between charts.

**[H2]** **Step 4: Plot the Control Chart**

Plot either duration of days to complaints or days until positive comments, depending on which is rarer. Check to see whether the duration exceeds UCL. Note that time-between charts are about a series of consecutive events and not about a specific point in the series. When you look at a chart for failure, for example, and see a string of consecutive failures, and one point of this string is above the UCL, the interpretation is that the entire series is unusual—not just the point that is above the control limit. Strictly speaking, time-between charts for failures should be drawn as the sum of continuous days of failure. This means that the chart would be on 0 for days of success, and when a string of failures start, would have no value until the end of the string, at which point will the value will be at the sum of days in the string. This produces a chart with many discontinuous events. To interpret the chart more easily, the analyst draws the days of failure from the start of the string until its end. So we draw the first day, the second day, and so on until the last day in the string of failures. This gives a more continuous feeling to the chart. Even though we have changed how the chart looks, the statistical tests are still done as before, on the end point of the series.

## [H1] Example: Analysis of Online Reviews

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| --- |
| Brief solicited patient reviews can replace long satisfaction surveys. Usually this results in higher response, more insights into patients’ experiences, and as quantitative benchmarks. |

Online patient reviews of clinical services, hospitals, imaging centers, and labs abound. Customer review portals have proliferated in recent years, and comments help patients select their clinicians. Online patient reviews require the patient to find the site and make a comment. Typically patients with complaints go through the effort if they were frustrated with their care. Others do not. An alternative to this passive data collection is to actively ask every patient to make a comment. These solicited comments provide a snapshot picture of the experiences of the patients with the clinic services and care. Solicited patient reviews can be a replacement for longer satisfaction surveys. They typically have higher response rate, provide more nuanced insights into patient experiences, are easier to complete, and, as we will show shortly, provide quantitative benchmarks for improvement efforts. These data can be used in quality improvement efforts. First reviews are analyzed for phrases and key words that can classify the comment as complaint or praise. Then time to complaints is used as a marker for patient satisfaction. The longer the time to next complaint, the better the situation.

Alemi and colleagues (Alemi et al. 2008) report soliciting comments from consecutive patients in a hospital-based clinic using a comment card. They asked each patient: “What worked well and what needs improvement?” The question can be asked by email or text (in which case the response is immediately available for analysis). It was asked through a comment card, in which the patient wrote his comment. Data were collected from December 12 through December 28, so a short interval. The receptionist handed the card containing the question and asked patients to respond and drop the card in a mailbox. No telephone follow-up was done to boost the response rate. Telephone follow ups are routinely done for long surveys because many patients do not respond. For short comments, there is less need for reminders or duplicate requests. Among the patients, 34 percent responded.

Exhibit 8.6 shows the comments provided in response to the open-ended question. These comments can be analyzed using time-between control charts, in this case documenting time to complaints. A computer or a human reviewer classifies comments into complaints or praise; some may be neither. Analysis of the responses in exhibit 8.6 indicated that there were many positive responses and four complaints. These complaints indicate how the clinic could be improved, even though the vast majority of patients are satisfied with care. Note that many of the patient complaints do not fit standard responses for patient satisfaction surveys. For example, two patients complained about discomfort during the process of care:

* “The medicine taken prior to the visit needs improving.”
* “All persons I dealt with were great. Anesthesia was very painful as it worked its way into vein and up arm. I don't name of drug, but it was white/milky.”

These two complaints suggest patient satisfaction can be improved if the medication is changed or modified. But, it may be that no realistic alternative medication exists, so satisfaction can be improved by better setting patients’ expectations. These complaints may also suggest areas in which research could improve the care process.

In exhibit 8.6, you will see that the patient from visit 34 had a complaint but attributed it to the entire office and not to specific groups of providers in the office. Satisfaction surveys limit patients’ ability to indicate if the comment is about the nurse, the doctor, or the receptionist. In this case, this patient would have had difficulty expressing views in a standard patient satisfaction surveys. The patient in visit 58 focused on the relationship between the anesthesiologist and other providers; again, this comment would be missed in many standard satisfaction surveys that typically focus on nurses and physicians. The point is that solicited patient reviews get to the nature of the patients’ experiences, unlike satisfaction surveys, which distort the report of these experiences by forcing them to fit predetermined close-ended response categories.

**Exhibit 8.6** Solicited Comments in an Outpatient Clinic

|  |  |  |
| --- | --- | --- |
| **Visit** | **Rating** | **What Worked Well and What Needed Improvement?** |
| 6 | Satisfied | Nurses were very accommodating to me when I realized I had forgotten my contact case. |
| 8 | Satisfied | (Marked as exceeding expectations) |
| 11 | Satisfied | Things were fine. |
| 14 | Satisfied | (Marked as exceeding expectations) |
| 18 | Satisfied | Everything worked very efficiently. |
| 20 | Satisfied | Loved my nurse, loved the cookie after my colonoscopy. |
| 22 | Satisfied | My nurses were really nice. |
| 23 | Satisfied | Very professional care: doctor and nurses were extremely nice. |
| 25 | Satisfied | From entry to exit the process moved along very smoothly. Great staff. |
| 29 | Satisfied | Great people—explain[ed] all procedures. |
| 31 | Satisfied | (Marked as exceeding expectations) |
| 32 | Satisfied | Nurses were great. |
| 33 | Satisfied | (Marked as exceeding expectations) |
| 34 | Not Satisfied | The doctor's office didn't give me orders and it was quite a hassle getting things done. |
| 38 | Satisfied | Very much pleased with the service. |
| 0 | Satisfied | (Marked as exceeding expectations) |
| 42 | Satisfied | BJ was wonderful nurse. |
| 45 | Satisfied | Ok. |
| 56 | Satisfied | Worked well—Ruby kept patient's family informed. |
| 58 | Not Satisfied | The anesthesiologist was curt and discourteous to one of her coworkers. |
| 59 | Satisfied | My nurse was very nice and this helped me to be comfortable. |
| 61 | Satisfied | Everyone was very friendly. |
| 62 | Satisfied | Nurse made me so comfortable. I had wonderful care from beginning to end. Bravo. |
| 64 | Satisfied | Staff was timely, procedure was painless. Overall very satisfied with my care. |
| 66 | Satisfied | Everyone treated me very well. After procedure they made coffee for me with cookie. |
| 73 | Satisfied | Do not have a response at this time. |
| 77 | Satisfied | (Marked as exceeding expectations). |
| 78 | Satisfied | Personnel were friendly, efficient, and highly capable. |
| 80 | Satisfied | Communication worked very well. |
| 81 | Satisfied | Everything was fine. People were outstanding. |
| 86 | Satisfied | Everything was fine. |
| 88 | Satisfied | All nurses were exceptional. |
| 95 | Satisfied | All went well. |
| 97 | Satisfied | (Marked as exceeding expectations). |
| 102 | Satisfied | Check-in very efficient. Staff is friendly with sense of humor; stamp [is] wasted for a drop-off card. |
| 103 | Satisfied | (Marked as exceeding expectations) |
| 105 | Satisfied | Zero problems. |
| 111 | Satisfied | Nothing. |
| 114 | Satisfied | Everything was great. |
| 119 | Satisfied | Lots of TLC for a very anxious patient. |
| 122 | Satisfied | The staff was professional, helpful and caring. Good experience overall. |
| 129 | Satisfied | (Marked as exceeding expectations) |
| 130 | Satisfied | All procedure were fine. |
| 133 | Satisfied | Staff very pleasant. |
| 137 | Satisfied | (Marked as exceeding expectations) |
| 138 | Satisfied | (Marked as exceeding expectations) |
| 146 | Not Satisfied | The medicine taken prior to the visit needs improving. |
| 147 | Not Satisfied | All persons I dealt with were great. Anesthesia was very painful as it worked its way into vein and up arm. I don't name of drug, but it was white/milky. |
| 148 | Satisfied | (Marked as exceeding expectations) |
| 149 | Satisfied | Everything worked well. |
| 150 | Satisfied | Nothing. (Marked as exceeding expectations) |

To create the control chart for this data, we calculated the UCL using the following steps:

Number of patients with complaints = 4

Number of patients without complaints = 47

Ratio *R* = 0.08



Exhibit 8.7 shows the resulting control chart. On the *y*-axis is the number of consecutive complaints. On the *x*-axis is visit numbers, which is another way of showing the passage of time. The straight line shows the UCL. The values above this limit are statistically significant and could not have occurred by mere chance. In this case, all four complaints are above the UCL and thus are statistically significant. This is reasonable, as this clinic has long stretches of no complaints. In a clinic where patients are almost always satisfied, a complaint would be considered an unusual event.

**Exhibit 8.7** Control Chart for the Outpatient Clinic

Alemi and colleagues (2000) also report use of solicited patient reviews in a different setting. These data were calculated on February 7th and 8th, again in a short interval. On exit from a pain clinic, the staff asked patients to comment on what worked well and what needed improvement by providing them with a comment card. Thirty-nine patients were asked to respond; of these, thirty responded (82 percent). Different physicians practice in the same clinic in different days. Data were collected over two days and the control limit was set based on the performance of the day with least consecutive complaints, so that benchmarked data would be available. Here are some of the complaints left:

* On visit 8: “When leaving reminder appointments, the message is often garbled. Helpful to speak more slowly.”
* On visit 10: “Everything was ok. Dr. was very late for my appt at 11:15am.”
* On visit 15: “Wait was too long.”
* On visit 24: “Doctor 20 mins late—this is my first appointment.”
* On visit 27: “Doctor needs to be on time. Front desk is great.”
* On visit 31: “Scheduling of appt behind—waited 30+ past appt time. Dr. was courteous and apologized for the wait.”
* On visit 32: “Would be nice to have magazines in lobby and room to help w/ wait.”

Solicited patient reviews provided the clinic with details about the nature of the complaints. Improvement teams in the clinic could use this information to guide their deliberations.

Exhibit 8.8 shows a control chart for the data obtained from the pain clinic. The control limit was derived from data on day 1 and used to examine data from day 2 (recall that different physicians practice in the clinic in these two days). As can be seen on day 1, there were three complaints, but the number of consecutive complaints did not exceed the UCL. Therefore, these do not suggest a departure from the normal pattern at this clinic. On day 2, there were fewer visits, but the frequency of complaints increased. The probability of a complaint on day 1 was 3 out of 23 visits (13 percent); on day 2, it increased to 4 complaints in 11 visits (36 percent). Exhibit 8.8 shows that the pattern of complaints during day 2 exceeded the control limit set from data on Day 1. Something was worse on the second day. Despite the small number of visits surveyed, the results are quite informative and show one instance in which there were two consecutive complaints. This was on the second day and at end of the day. This may suggest that more attention should be paid to satisfaction with care on this day or the situation at the end of the day.

**Exhibit 8.8** Consecutive Complaints of Satisfied Patients in the Pain Clinic

UCL

If the observations exceed the UCL, then these observations are unlikely to have occurred by chance. They signify a change in the underlying frequency of the event being tracked. If the control limits were based on pre- or post-intervention periods, observations above the control limit indicate the impact of the intervention. Of course, it is possible that the change in probability of the event might result from another event not tracked in the control chart. Therefore, attribution of change in the probability of the event to the intervention should be made with caution. The chart in exhibit 8.8 shows that in the pre-intervention period, patients had two strings of consecutive complaints. In the first string, patients complained four times in a row. In the second string, patients complained two consecutive times. Both strings exceed the UCL. Compared to the post-intervention period, these two strings of complaints are long enough to constitute a real change in the process. Based on these findings, we conclude that the intervention was working and the rate of complaints has dropped.

## [H1] Example: Keeping to Exercise Resolutions

Individual personal improvements often fail to last. A person loses weight but then rapidly gains it back. Another person joins a gym to exercise more but soon after fails to take advantage of the membership in the gym. On January first, many make resolutions that they do not keep. These widespread personal failures to change stand in contrast to organization’s efforts, where process improvements last. When change occurs inside an organization, the process seldom reverts back to previous procedures. The success of process improvement teams in work settings has led to many trying these techniques on personal improvements (Alemi et al. 2000). Patients are told to change the process of their lives, engaging other process owners in finding a solution. Patients are told to rely on changes in their daily living processes and not on their motivation or effort. They are also asked to keep data on their progress.

Exhibit 8.9 shows data collected over 18 days by a 35-year-old woman trying to exercise more. This patient was asked to make a process change and track her progress. She decided to take morning showers at the gym and thus combine her exercise and shower routines. Clearly this is a process change in her daily living activities. The question remains if she has been successful in keeping up with her resolution. The first ten days show the data before the change; the remaining days show the data after. Has the shift led to increased use of the gym?

**Exhibit 8.9** Exercise Patterns for One Patient before and after Process Change

|  |  |  |  |
| --- | --- | --- | --- |
| **Day** | **Exercise Resolution Kept?** | C**onsecutive Missed Exercise** | **Process Change** |
| 1 | No | 0 | No |
| 2 | Yes | 1 |
| 3 | Yes | 2 |
| 4 | Yes | 3 |
| 5 | No | 0 |
| 6 | Yes | 1 |
| 7 | Yes | 2 |
| 8 | No | 0 |
| 9 | No | 0 |
| 10 | No | 0 |
| 11 | No | 0 | Yes |
| 12 | No | 0 |
| 13 | No | 0 |
| 14 | No | 0 |
| 15 | No | 0 |
| 16 | Yes | 1 |
| 17 | No | 0 |
| 18 | No | 0 |

The control limit can be calculated from either the pre- or the post-process change, whichever leads to a lower UCL. In this case the control limit is calculated form the post-intervention data, the data for days 8 through 18, because it has the least variability. There are one missed day and eight exercise days. Therefore, *R* is calculated as 1/8 = 0.13. The UCL is then calculated as:

To construct the control chart, we need to use the rules in exhibit 8.5 to calculate the number of consecutive days of missed exercise in exhibit 8.9. The second column in exhibit 8.9 shows the calculated number of missed days of exercise. Note that the number of consecutive missed exercised increases until a day of exercise, at which point the number is reset to zero.

Exhibit 8.10 shows the resulting chart and control limit. This exhibit shows that several points in the pre-intervention period fall above the control limit. Therefore, there is a statistically significant difference between the two periods: the pre-intervention period has more consecutive missed exercise days. The person can thus conclude that the process changed led to improved pattern of exercising.

**Exhibit 8.10** Control Chart for Time to Complaints

## image012

**[H1] Are Insights into Data Worth the Effort?**

The point of any control chart is to show data that will help improvement. The effort we put into measurement and analysis is wasted if it does not help us improve. Too much analysis could lead to paralysis. Constructing a control chart is time-consuming and, for some, difficult. But what is the alternative? Many people err in detecting real changes. They mistake random fluctuations in patient experiences for real change. A balanced approach is needed in which one relies on data but also leaves time and effort to make improvements. Control charts help discipline our intuitions to see beyond occasional complaints or random outliers and focus on patterns.

# [H1] Summary

This chapter showed how sentinel events could be analyzed through time-between charts. We introduced the concept of geometric distributions and then used these distributions to construct time between control charts. Rare events can be captured through these types of charts.

# [H1] Supplemental Resources

Problem set, solutions to problems, multimedia presentations, SQL code, and other related materials are in the course website.

# [H1] References

Alemi, F. 2007. “Probabilistic Risk Analysis Is Practical.” *Quality Management Healthcare* 16 (4): 300–310.

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