

Correspondence

Monitoring peak flow using control charts: Comments from experience

To the Editor:

Gibson's article in the Journal¹ invites all of us to reflect on the use of control charts in the care of patients with asthma. Because the focus of my research for the last 6 years has been just this and because I made mistakes before learning how this is best done, I hope the following technical and clinical comments regarding the construction and application of control charts in the care of patients with asthma will be helpful.

First, both the Gibson¹ article in the Journal and the Gibson et al² article in the *Annals of Internal Medicine* contain a fatal flaw: each violates Shewhart's³ requirement for homogeneous data (now referred to as rational subgrouping). The fatal flaw is called *irrational subgrouping*.⁴ The basic concept of rational subgrouping is that only data collected under similar conditions should be placed on the same chart. Clearly morning and evening peak expiratory flow rate (PEFR) values are not gathered under the same conditions (diurnal variation). Neither would any set of prebronchodilator and post-bronchodilator observations be considered rational. The use of non-homogeneous data (irrational subgrouping) is a fatal flaw because it (1) distorts the ± 3 sigma limits (± 3 sigma widens) (2) adversely affects the construction of additional chart features important to the recognition of other signals, (3) makes accurate interpretation of the chart impossible, and (4) invites misinterpretation of the data so charted. All of this interferes with the intelligent clinical use of the charts. Gibson's recommendation to chart morning and evening PEFRs is in violation of Shewhart's basic rule. In his defense, it is an easy mistake to make—I made it when first beginning to use this concept—given the morning-evening paradigm within which most of us have been taught PEFR must be monitored.

Second, the type of control chart Gibson used was not defined for the reader, nor was the method for deriving the ± 3 sigma values made explicit. It is important for the reader to know both, to be able to assess the validity of what is presented. The ± 3 sigma limits are not derived from simply the population of PEFRs measured but from a mathematical integration of this knowledge and knowledge of the serial variation between the observed PEFRs. It is important to know that the limits were calculated in this manner. If not, Shewhart's method has not been correctly applied. One can refer to the literature for details on control chart construction in asthma.⁴⁻⁷

Third, "signals" on control charts do not equate with the patient being out of clinical control; they indicate only that there has been a statistically significant shift in the measurement process (PEFRs or FEV₁s). Indeed, a person with asthma can be (1) in statistical control and in clinical control, (2) in statistical control and out of clinical control, (3) out of statistical control and in clinical control, and (4) out of statistical control and out of clinical control. Differentiation between these 4 groups is basic.

Fourth, control chart signals can herald either improved function or reduced function—not just reduced function—and can occur in patients and not in clinical controls. There are helpful signals on control charts that occur within ± 3 sigma limits, not just outside these limits.⁴⁻⁷ Some of the most clinically helpful signals I have seen have been improvement signals in persons in clinical control! The latter speaks to the power of the charts.

Fifth, I and others have suggested an XmR type of control chart with the morning prebronchodilator PEFR or FEV₁ used as the indicator value, with X being the serial morning prebronchodilator observation and mR the serial moving range variation between morning observations.⁵⁻⁷

Sixth, it is important for readers to realize that control charts do something we in asthma care often talk about but rarely do: integrate serial flow rate data with their parallel serial variations. This is done mathematically in control charts and determines the construction of the chart. The latter affects its interpretation and clinical usefulness. Integration of actual serial flow and serial variation is a key reason control charts are potentially helpful in the care of asthma.

It is very important that this "new" theory and its methods and tools be used properly, lest we miss the practical knowledge it can provide, misinterpret what it says, and miss the opportunity to help our patients in a manner that is not otherwise available.

Peter B. Boggs, MD, FAAAAI
The Asthma 2000 Group
4817 Gilbert Dr
Shreveport, LA 71106

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Reply

To the Editor:

I thank Peter Boggs for highlighting the utility of quality-control analysis in asthma care and for prompting a comparison of different methods for constructing control charts. In his letter, Dr Boggs questions the use of morning and evening peak expiratory flow (PEF) to construct control charts for improved monitoring of asthma. When the same patient measures the same parameter (PEF) on the same day using the same instrument, it is indeed rational to view these measures as part of the same process, particularly when that process is the defining characteristic of asthma (increased variability of flow). In fact, there may be disadvantages to using once-daily PEF because other conditions that cause airflow limitation without increased variability (eg, chronic obstructive pulmonary disease, bronchiectasis, infective bronchitis) could confound the interpretation of results. We compared the utility of morning/evening PEF control charts for detecting exacerbations with usual PEF action points and found that they performed significantly better than conventional measures.¹ Therefore, use of morning and evening PEF to construct control charts is not only rational, it is a demonstrable improvement over current practices.

Dr Boggs has been claiming our approach is "fatally flawed" since at least 1998.² No data have been produced to systematically compare the two approaches, and we are asked to accept his theo-

retical arguments that are based on inaccessible papers from experts. I am floored, but not fatally, by this approach. Expert opinion has its limitations (see Table 1 in our article³). Clearly, the way forward is to systematically and prospectively evaluate the two approaches to constructing control charts. Outcomes should include not only assessment of asthma exacerbations but also perceived utility and use of the two approaches by clinicians.

Are the approaches likely to be different? We constructed charts using valid statistical procedures contained in Minitab Statistical Software (Stage College, Pa) and used 8 different measures as well as several types of charts. We reported the 3 best measures,¹ and of these, the 3-sigma limit is the simplest to use on a practical basis. The main limitations are conceptual and practical difficulties in educating clinicians about how to use control charts and also the potential for false-positive results (out of statistical control and in clinical control). Because the 3-sigma limit performs as well as the other tests and is the simplest to use, it was described in the review article. Of course, other tests can be used, such as the XmR chart proposed by Dr Boggs, which is mathematically more complex. But again, we need prospective comparative data on their utility for patients and clinicians before making things unnecessarily complex. It is unlikely that other tests will be better at detecting exacerbations because the success rate of the tests we used was very good at between 84% and 91%. The false-positive rate of these tests was 20%, and any method that reduced false-positive results would be welcomed.

We have demonstrated the utility of control charts in detecting

exacerbations of asthma. It is likely that there are other important uses for control charts in asthma management, such as defining asthma control, detecting triggers, investigating asthma mechanisms,^{4,5} and evaluating response to therapy. To move forward in these areas as well, we need to replace unsubstantiated assertion with systematically collected prospective data.

*Peter G. Gibson, MBBS, FRACP
Respiratory Medicine
John Hunter Hospital
NSW 2310, Australia*

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