Notes on variation and systems ahead of Statistical Process Control Charts seminar for the Healthcare Infection Society

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Introduction

Hello everyone, and thanks for signing up for the HIS Trainee education day on **Behaviour change, quality improvement and leadership.** My session will focus on statistical process control charts (SPCs). We planned to have a face-to-face workshop, with everyone bringing their own data and producing their own chart, going home with a newfound appreciation of SPCs and quality improvement. Alas COVID and *the best laid plans of mice and men*…

So first an introduction to me. My name is Evonne, I am a doctor of nursing (which I know is a contradiction in terms). I have been working in infection control since 1988. Apart from my outbreak work and work on intravenous systems, my other infection control key area is SPCs. I was first introduced to SPCs back in 1998 with the work of Jim Benneyan, he wrote 2 seminal works (links below). I was fortunate to have been in correspondence from 1998 and still am to this day. If you have the time to read any of his papers please do so. I first used SPCs in 1999 and have used them ever since. The chart project (an RCT on SPC usage – link below) was one key output.

Online seminars are more challenging for the audience to remain focused on, so I am shortening the time of watching with a brief introduction to *variation* and *systems* here. If you consider you are content with your understanding of variation and systems, then I'll see you at the seminar. If not please read on…

Variation:

For SPCs variation is defined as either 'natural' or 'unnatural'. [Some people alternatively use the terms *common cause* and *special cause* variation]. I recommend *natural* and *unnatural* variation – it is easier to explain to others. Now that is key because what you are trying to do with SPCs is communicate. So, simplification matters (you will lose some people with the first word 'statistical'). You may use SPCs to improve your own work or that of a microbiology dept; but I am assuming you are wanting to do some healthcare quality improvement (QI) in clinical areas. In these areas you will have to convince colleagues that their systems are possibly awry and need change. SPCs are all about identifying variation, but more importantly they are about communicating that variation and what needs to happen consequently.

SPCs distinguish between variation that is *natural* or part of the system or *unnatural* something outwith the system's normal function.

SPCs that are exhibiting natural variation are in statistical control.

SPCs that are exhibiting unnatural variation are out of statistical control.

Note 1: Telling a manager that one or more of their wards are out of statistical control is powerful.

Note 2: You can be out of statistical control in a positive as well as a negative sense.

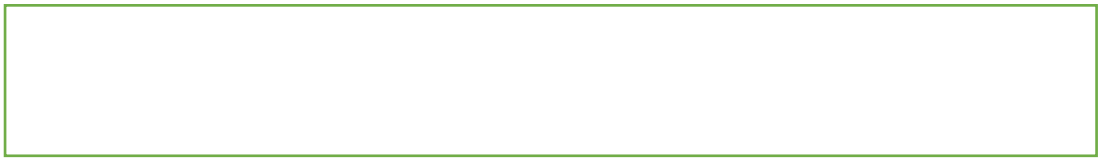
Back to variation: Consider your commute to work - what is the time range before you would consider it exceptional? Let's say you are normally at your place of work give or take a 20-minute slot. This is natural variation. You aim to arrive around 8am. If you arrived at 08:00 today, 08:10 tomorrow and 07:50 the next day, the 08:00 arrival is not an improvement on the 08:10 nor a deterioration on the 07:50, these times are all exhibiting natural variation.

But what about a day when it all goes wrong. A train stops due to a tree on the line and you eventually get in at 10:00. This is not *natural* but *unnatural* variation. Something in the system of bringing you to work has gone awry.

The best explanation of variation being either natural or unnatural was by Mohammed A Mohammed (link below) and I am going to steal it from him.

Write the letter A in the first box.

Excellent. This is just the type of letter A that I want to buy. Please could I have 6 more letter 'A's' in the larger box.



Hang on a minute – these are not the same. They are different. But you did them with the same pen in the same environment, by the same operator – why are they not the same? This is the natural variation in your system of writing the letter A. Now write one more letter A with your other hand.

This is unnatural variation. A less experienced hand has produced this poor-quality letter A.

If you wanted to reduce natural variation you would have to change the system, e.g. use a typewriter, or a computer – the letter 'As' would still vary, but that variation would be much reduced.

If you wanted to get the unnatural variation back in control you would have to get your alternate hand some practice.

So, this is key. With SPCs you are looking to classify variation as either natural or unnatural. If its natural its part of the system. If you want to get this system to reduce errors, you are going to have to make an improvement change within the system. With unnatural variation you need to determine what has caused the system to go awry and then eliminate it.

Let's apply this thinking to healthcare QI example. Contaminated blood cultures are a waste of resources, lead to erroneous diagnoses, result in amongst other things the changing of uninfected lines, prescribing unneeded antibiotics and the seeding of lines.

Ward A has a contamination rate of 6% - they don't know it as no one has told them. If we want that rate to change, we have to change the system. If they suddenly go to 20% we have to find something affecting the systems normal function, e.g. contaminated antiseptics, contaminated containers, new procedure, risky HCWs etc., etc. Now let's look at systems to find candidates to change.

Systems

What do we mean by systems and what schematics are useful for us to understand and describe them.

Clinical Microsystem (CMS)

The smallest unit of healthcare is called a clinical microsystem (CMS), e.g. a single ward or a theatre. Patients enter the microsystem, treatment happens, and they leave the microsystem to enter another microsystem or leave the health system altogether. Whilst in this system resources are utilised. A CMS is the unit of care where most of our problems happen, consider most outbreaks usually happen in a single ward CMS. There is no point feeding back data at a hospital level if you want improvement in a single microsystem. Data (or better still intelligence) is needed relate to their and only their unit – unless you want to compare one unit to another. This is a very useful concept for healthcare QI. See papers below and link to clinicalmicrosystems.org.

Another chart that is essential for healthcare QI is the fishbone or cause and effect chart. (See one at the bottom of this paper). I have changed the elements over time to best depict a CMS and what is needed in it for optimal IPC. If you go back to the Coia et al 2006 MRSA guidelines, it contains a fishbone chart and somewhere below it is my name. The one at the back of this paper is different as the more you learn about systems the more you understand them and modify how you illustrate them. I sometimes write this as everything needed to get to a goal (at the head of the fish - box on the right). And I sometimes write them as everything that can go wrong. It does not matter which. The one at the back is everything you need to have optimal IPC within 7 elements: 1) people (which I specify as Patients, HCWs and Visitors), 2) the environment (physical), 3) the culture of the environment, 4) equipment, 5) methods 6) intelligence and 7) micro-organisms.

So the SPC chart will tell you that there is something wrong with the system by detecting unnatural variation, and a fishbone chart will identify everything it could be that is making the system go awry. There is one further chart which is of use in this situation and that is a Pareto chart. A Pareto chart lists the frequency of errors in each possible category of errors. For example, for line infections, the number 1 cause of an increase could be: not making up drugs aseptically or not using antiseptic as required. Now no one will have that data unless someone specifically collects it. But sometimes just going to a ward with a cause and effect chart and asking “Tell me where we are going wrong…” will yield results. I have gone to wards with this chart and they know without looking what the problem is, e.g. shortage of staff, failures to isolate, lack of x, y or z.

So there you have it. SPCs will tell you there is a problem (unnatural variation) but not what the problem is. A cause and effect chart will list all the possible causes of that problem. And a pareto chart (if you have the data) will tell you what the most likely cause is.

SPCs are technically easy to understand. What is harder to do is to communicate the variation, the importance of needing to change a system, and motivating people to change and to keep that improved system working in statistical control.

In the webinar I am going to show you how to make up SPC charts and how to interpret them. I will show you how mistakes are easily made in producing SPCs. I won’t focus on the improvement part. But if you want another session on that, well HIS know where to get hold of me.

Footnote software can do this – produce SPCs but they get it wrong (I’ll show examples of this). Don’t rely on software. SPCs are a shop floor tool and any person, on any production line can a) produce them and b) understand them. Benneyan does not recommend software and neither do I.

Tip: get ready to produce a chart – but look for *cheap as chips* data. Here is one example:

• Use a definition of a contaminated blood cultures that your lab system can extract a) the number of contaminated cultures and b) the total number of contaminated cultures taken by each ward.

• Select a ward / unit with a high rate.

• Get that data for the past 25 units (weeks or months) ….

• [If you have a pet project ready to go great – just 25 units of data please]

• Get ready to make an SPC when you come back from the seminar…

Not suggesting your read everything – but have a look at some of it. Juran's quality handbook would be welcome in any lab library…. And Christmas is coming…

Benneyan's seminal works	https://pubmed.ncbi.nlm.nih.gov/9552190/ https://pubmed.ncbi.nlm.nih.gov/9605277/
The Chart project	https://pubmed.ncbi.nlm.nih.gov/18723251/
Mohammed paper on variation	https://qi.elft.nhs.uk/wp-content/uploads/2018/10/Shewharts-Forgotten-Lessons.pdf
Book on systems – recommended if you want to understand systems	https://www.amazon.co.uk/Systems-Thinking-Creative-Holism-Managers/dp/0470845228
If IHI are the evangelists of healthcare quality improvement, Dartmouth, is the brains. Their work on clinical micro-systems is genius and papers online	http://www.Clinicalmicrosystem.org
Using data to prevent and control infection… has a schematic of a clinical support microsystem	Wilson curran.pdf
The IPCT as a clinical support microsystem	using data 2011 curran.pdf
Coia et al 2006 MRSA guidelines	https://pubmed.ncbi.nlm.nih.gov/16581155/
Information on the Pareto principle	https://improvement.nhs.uk/documents/2137/pareto.pdf
If you are going to get into quality improvement now is an excellent time.	

Culture

HCWs are mindful of their patients' vulnerability to infections, and of the outbreak risks within their clinical setting.

HCWs are focused on achieving IPC excellence through the avoidance, detection and negation of infection risks.

HCWs continuously update their IPC situation awareness and use this assessment to optimise decision-making.

HCWs actively seek and give feedback to optimise care and keep patients safe.

HCWs report when identified risks cannot be eliminated within allocated resources.

Methods

Standard Infection Control Precautions are used to prevent cross-transmission and cross-infection:

Hand Hygiene – as per WHO 5 moments
Safe use of **Personal Protective Equipment**
Safe **Patient Placement**
Safe use and disposal of **Sharps**
Safe disposal of **Blood & Body Fluids**
Safe disposal of **Waste**
Safe use and disposal of **Linen**
Safe **Equipment** – next-patient-condition-ready
Safe **Environment** – clean & decontaminated
Safe **Respiratory hygiene**
Safe **Invasive Device** use – only used if unavoidable, aseptic technique followed, devices monitored & devices removed as soon as clinically indicated
Safe **Preparation of IV drugs.**

People: Patients, HCWs & Visitors

People who enter the care facility are mindful of the infection risks presented by patients and themselves. They act in of the best interests of the patients.

There are enough suitably trained HCWs to facilitate safe IPC procedures. IPC training deficits are identified and met.

HCWs present themselves professionally: clean uniforms, 'bare below the elbows', tidy hair, *absence of wrist-watches, stoned rings, false nails and nail-varnish.*

There are effective communications between HCWs, patients and their visitors on infection risks and they are minimised.

Physical Environment

The environment is fit-for-purpose, visibly clean, decontaminated and designed to optimise and promote IPC safety with:

- Enough beds, bed-spacing, single rooms, wash-hand basins wash-hand sundries and alcohol-based hand rub.
- Adequate ventilation, safe water and taps that minimise infection risks.
- Cleanable and intact surfaces.
- Sufficient resources to keep the environment safe.

There is accessible up-to-date guidance on the IPC procedures, and the actions to take if environmental deficits are detected.

Equipment

There is enough equipment to facilitate individual patient allocation, where needed or adequate decontamination between patients / usage.

Available equipment is fit-for-purpose and able to withstand recommended decontamination procedures.

Materials for equipment decontamination are available and how-to-decontaminate guidance is displayed.

In-use and in-store equipment is clean and free from any spillages.

There is sufficient HCW time for effective equipment decontamination after use and between patient use.

Intelligence

There are current data to indicate IPC performance and local IPC risks e.g.: alert organism incidence, BSI, SSI, hand hygiene, antimicrobial prescribing and invasive device care.

Data are valued. Data are examined for indicators of failure and to ID ways to improve safety.

External data are used to compare performance and assess achievements.

Optimal Infection Prevention & Control (IPC)

To minimise outbreaks, people who may present infection risks to others are screened (and if required isolated).

Micro-organisms inc abx resistant