



POLQM Quality Conference

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ISO9001:2015

A Quality Option for the Medical Laboratory (?)

Michael A Noble MD FRCPC

Department of Pathology and Laboratory Medicine

University of British Columbia

Vancouver BC Canada

Warning

This presentation is
“Quality Wonky”



If you can stay engaged
for the next 20 minutes
or so, you are a real
“Qualitiphile”.

Declaration

1

I am a laboratory physician with a long time interest in Quality Management and Quality Improvement, for the medical laboratory. I am a self-declared Medical Laboratory Qualitologist.

2

I have sat on committees committed to the development of quality standards for about 35 years (including ISO TC176 and ISO TC212)

3

I have direct experience in laboratory quality management in institution based and community based medical laboratories as well as laboratories associated with research development

Relevant Story Number 1

In 2002 I was shamed into pursuing international recognition for CMPT, my proficiency testing program by a laboratory technologist who accused me and others associated with laboratory oversight as being **FRAUDS** because we exerted our authority over laboratories making performance demands while at the same time requiring no similar demands on ourselves.

She was disturbingly absolutely correct.

In the absence of another credible quality standard (at the time) we immediately started our process towards have our quality system developed and certified to ISO9001:2000(then)

Relevant Story Number 2

- In order to implement our voluntarily imposed quality system, we hired a quality consultant. One day he called me aside and pointed out that when he was around, I would work with him on the QMS.
- When he was NOT around I would STOP working.
- Josef made it clear: “This NOT his QMS, and was NOT his laboratory. If I wanted this to actually happen, I would have to take ownership and get my act in gear”.
- ***Again, he was embarrassingly correct.***

The saga
continued...

*We got ourselves going,
completed our certification
and have maintained it ever since.*

*By every measure CMPT improved
substantially and has grown from
being a local program to a national
and now international EQA provider*

*In 2014 we extended
our commitment to quality
and added international accreditation
(ISO/IEC17043:2010).*

The Lessons we Learned

The impetus and
inspiration to Quality
can come from
the most unexpected of
places, but...



The drive and motivation
to Quality
must come from within.
Nobody can do it for you

After 17 years of
experience with
ISO9001:2008-2015
(now)

I continue to see ISO 9001
as being sound, productive and
sustainable and critical basis for
quality
even in a non-traditional areas
as medical laboratories.

In those areas where
accreditation to another standard is
mandated, ISO 9001 can be a
valuable supplement to enhance
Quality Improvement

Things that I like
about
ISO9001:2015

1. Things that are written well
 1. The Principles of Quality Management.
 2. Opportunities for Improvement
 3. Imbedded Quadrilateral Risk-Based Thinking
 4. Customer Expectation
 5. Quality Planning
2. Things that are NOT written
 1. Determination of Causes.
3. Opportunities for Improvement that would enhance its application in the medical laboratory (in my opinion)

Reason #1
**ISO 9001:2015 incorporates
The Principles of Quality Management**

Customer focus*
Leadership*
Engagement of People*
Process approach*
Improvement*
Evidence Based Decision Making*
Relationship Management*

**Note: These principles are stated in the preamble of ISO9001:2015, but more thoroughly described in ISO9000:2015 (QMS: Fundamentals and Vocabulary)*

The Principles of Quality Management

Customer focus	Meeting customer requirements / satisfaction
Leadership	Unity of purpose to achieve Quality objectives
Engagement of People	Competent, empowered and engaged people at all levels throughout the organization
Process approach	Consistent reliable results through activities that are understood and managed as a coherent system.
Improvement	Ongoing focus on continuous improvement.
Evidence Based Decision Making	Decisions based on the analysis and evaluation of data
Relationship Management	Manage relationships with relevant <i>interested parties</i>

Why I think this is
important

By incorporating the
Quality roadmap
into the standard
it reminds the reader there is
purpose to the requirements.

Reason #2

ISO9001:2015 emphasises “Opportunities for Improvement” as often as Nonconformities

Nonconformities

- Finding of activities that are non-fulfilments of *requirements*
- **A negative observation**
 - A “shall” statement not addressed
 - Promotes adherence rather than variation.
 - Penalizing and Regressive

Opportunities for Improvement

- Finding of activities that can enhance *performance*
- **A positive observation**
 - *An activity that can be improved or performed better.*
 - *Stimulates innovation and initiative*
 - *A step forward*

Why I think this is
important

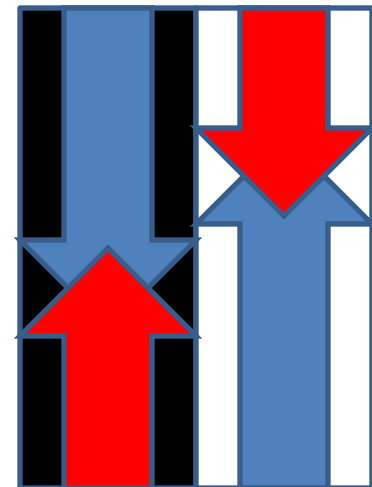
By emphasising
opportunities for improvement
as a integral part of the standard,
it shines a light
on the importance of
innovation and progress
in the Quality Process

Reason #3

ISO 9001:2015 imbeds

“Quadrilateral” Risk Based Thinking

- When planning the organization shall consider both internal₍₁₎ and external₍₂₎ issues and determine the risks₍₃₎ and opportunities₍₄₎ that need to be addressed to:
 - give assurance that the quality management system can achieve its intended result(s);
 - enhance desirable effects;
 - prevent, or reduce, undesired effects;
 - achieve improvement.



Why I think this is
important

By emphasising
the multidimensionality of risk
as a requirement
it broadens the planning process
to a more thorough view of
opportunities and threads

Definition of Customer:
customer is a person or organization that could or does receive a product or a service that is intended for or is required by this person or organization.

What is Customer focus:
The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.

Reason #4
ISO
9001:2015
makes
extremely
clear the
importance
of the
customer.

Requirements for Customer Focus -1

- Communication with customers shall include:
 - providing information relating to products and services, handling enquiries, contracts or orders, including changes
 - obtaining customer feedback relating to products and services, including customer complaints,
 - handling or controlling customer property and
 - establishing specific requirements for contingency actions, when relevant.

Requirements for Customer Focus -2

- The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.

Requirements for Customer Focus -3

- The management review shall be planned and carried out taking into consideration information on customer satisfaction and feedback from relevant interested parties;
- The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.
- this International Standard is applicable where an organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.

Why I think this is
important

At a time when customer expectations have never been higher, and competition has never been more active, this standard elevates the importance of customer focus and satisfaction beyond the level of projects and exercises and integrates it into the centre and core of the Quality Process.

Theranos may have failed, but it doesn't mean that the interest in better faster performance has gone away.

As a side note I think there is still room for improvement even in this standard

1

What is Customer focus:

The primary focus of quality management is to meet customer requirements *within the reality and limitations of the product or service* and to strive to exceed customer expectations.

2

ISO9001:2015 speaks of only TWO tiers of customers, Customers, and Interested Parties both with its own expectations. I think there is a third group.

Customers:

Patients and Clinicians

Interested Parties:

***Family, Friends
Laboratory Staff, Public Health***

Stakeholders:

Regulators, Insurers, Litigators,

Reason #5

ISO 9001:2015 provides flexibility to
Determination of Causes

ISO 9001 throughout has used the term
Determination of Causes
as opposed to
Determination of *Root* Causes.

(the word “Root” never occurs in ISO9001)

Why I prefer the ISO 9001:2015 view of Determination of Causes

With the exception of situations with
recurrent repeated error
or immediate detection error
or machine mechanical error,
in labor intensive organizations
searching for a root cause
too often leads to
indeterminate or false conclusions.

Chaos theory: Causes through Chaos

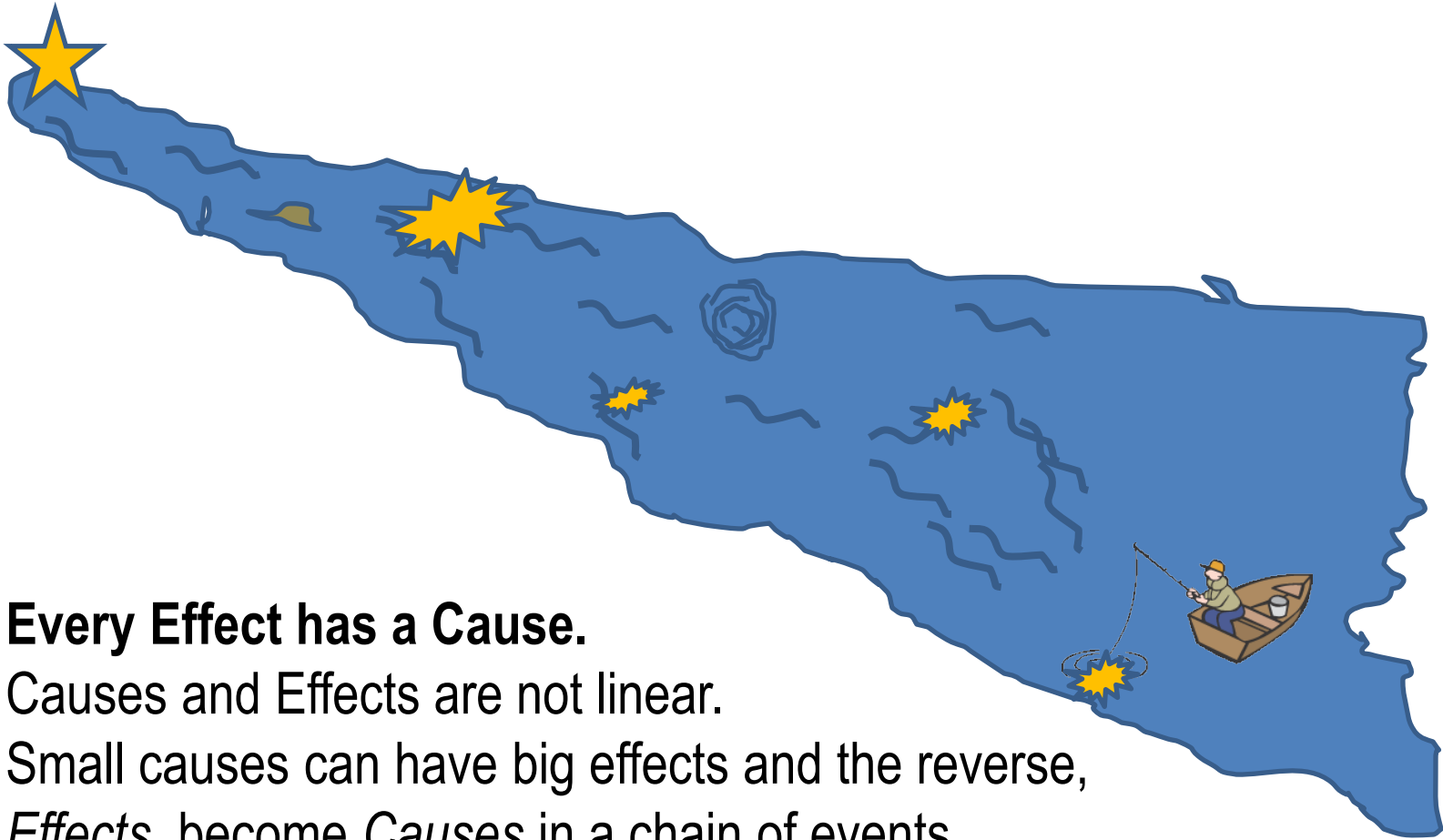
First developed by Edward Lorenz, a meteorologist and mathematician

A mathematical model developed to explain the unpredictability of weather (1960s).

Has application on the behavior of any dynamic systems that is highly sensitive to initial conditions and is subject to change

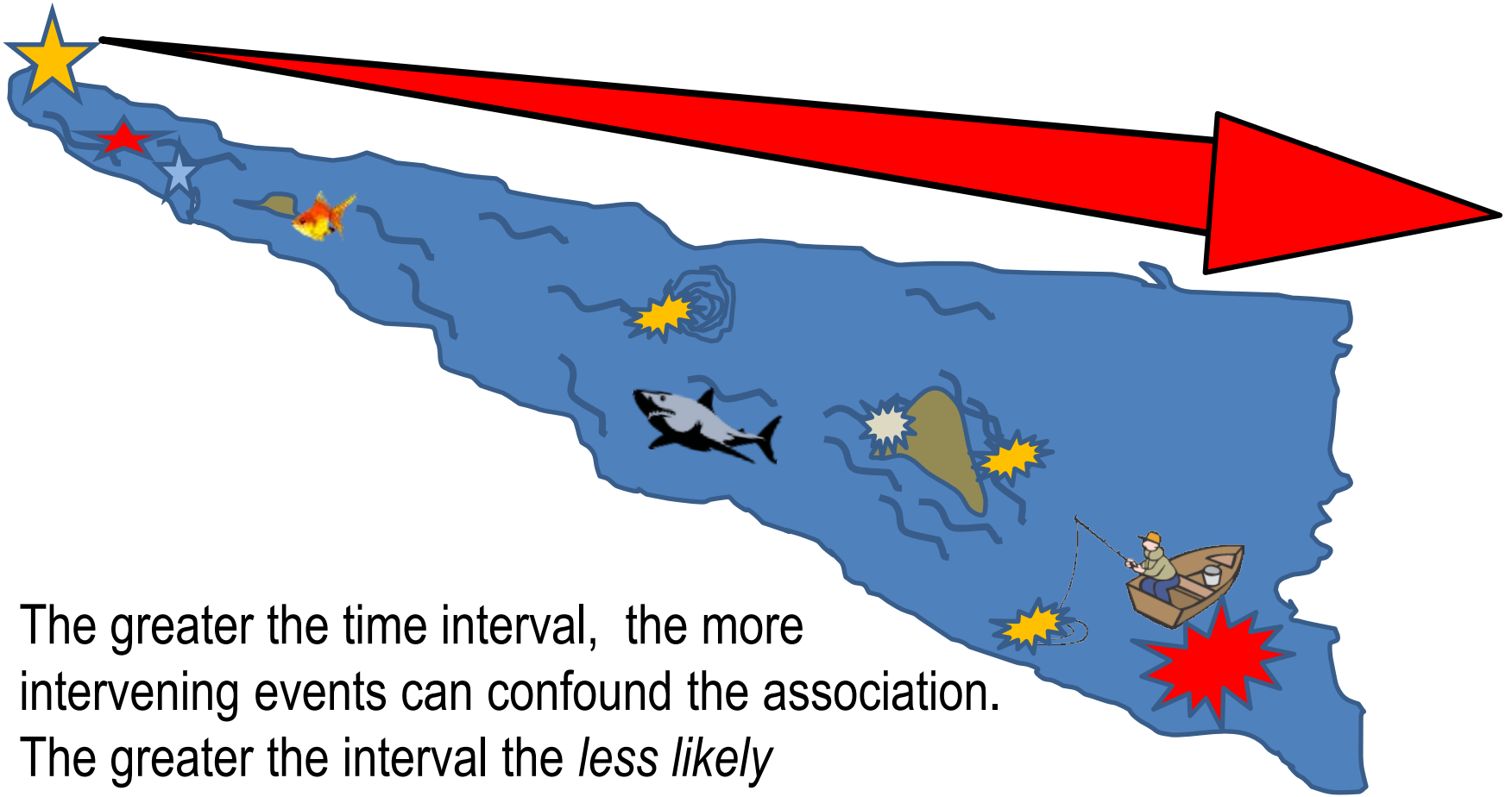
“butterfly effect”
the flutter of a butterfly’s wing in New Mexico causally linked to hurricanes in China.
Small causes can have BIG effects.

What Chaos Theory Teaches about Cause and Effect



- **Every Effect has a Cause.**
- Causes and Effects are not linear.
- Small causes can have big effects and the reverse,
- *Effects* become *Causes* in a chain of events.
- A Cause can result in many Effects.

“the uncertainty in a forecast increases exponentially with elapsed time”



- The greater the time interval, the more intervening events can confound the association.
- The greater the interval the *less likely* an association can be determined.

Associations with Human Error

Individual Causes

Distraction
Discomfort
Stress
Emotion
Inhibition

Disruption
Disease
Fatigue
Lapses
Triggering

Systemic Causes

Unlike Machines, Human Responses to the Erratic, Subtle, Noxious, Suppressive and Biased Influences create untold variability on Awareness and Focus

Lorenz and Chaos Theory

Point out Two Critical Lessons

- When it comes to finding associations between Cause and Effect...
 - Two highly improbable events may be causally linked.
 - Two seemingly probable events may not.

Defining causal links is often more a function of probability and less a function of certainty.

Determining a Probable Cause or a Most Probable Cause is a more honest conclusion

Why I think this is
important

Using the term
“Determination of Causes”
does not exclude the use
of Root Cause Analysis,
but it opens the
investigative process to
alternatives.

So why do I think ISO9001:2015 is an excellent document for the medical laboratory...

- It provides a roadmap and principle process to quality.
- It highlights the importance of Customer Focus in an era when our customers are expecting and demanding more.
- It highlights a positive view to improvement at a level equal or better than addressing non-conformities.
- It highlights a different approach to planning through more active examination of risks and benefits.
- It offers flexible language and choice when providing solutions and improvements rather than rigidity.
contrast that to the rigid requirement for uncertainty of measurement

So what can Laboratory Quality Managers do?

- Evaluate ISO9001:2015 (and ISO9000:2015)
- Decide to:
 - “cherry pick” the features found in ISO9001:2015 that are NOT found in other documents
 - voluntarily introduce the standard into your regular quality improvement process. Supplement this with a series of “external – internal” audits
 - seek supplementary/voluntary certification to ISO9001:2015
 - Not bother (do nothing).

In Conclusion in MY opinion...

Laboratory Quality Managers are always be on the look out for newer and different and better (?) approaches to Quality.

ISO9001:2015 deserves a look.