



improving processes

Keith's Question Corner

Today's question: "How can we use KPIs to add value?"

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Note: this webinar is being recorded

Keith Dorricott



- Lean Sigma Master Black Belt with 18 years' industry experience
- Formed DMPI in 2016. Engagements with vendors, CROs and Pharma including:
 - Development of KPIs for Sponsor-CRO collaboration
 - Process mapping and identification / prioritization of improvements
 - Senior RBQM Trainer for Cyntegrity
 - Senior Consultant for AQC leading work groups on metric development & use e.g. DCT
 - Critical thinking training on RBQM, root cause analysis, data interpretation
- Member of Scientific Advisory Board for King's College, London – Centre for Pharmaceutical Medicine Research



What do you want to learn?

Timing and display/documentation of oversight reviews occurring

Is it the KPI that needs the most improvement or is it the process e.g., moving to QbD. Including for the optimization of KPIs?

Critical conversations regarding KPI establishment and revisions between Sponsors/CROs

How to avoid "Death by KPIs"?

Which leading indicators have people used that have proven to be effective - how were they used?

How to build a proper technology and good KPIs and KRIs

To share experience

KPIs, KRIs, and QTLs

ICH E6

From this...

5.2.2.

Any trial-related duty and function that is transferred to and assumed by a CRO should be specified in writing.

ADDENDUM

The sponsor should ensure oversight of any trial-related duties and functions carried out on its behalf, including trial-related duties and functions that are subcontracted to another party by the sponsor's contracted CRO(s).

ICH E6 (R2)

To this...

- 3.6.9 The sponsor should have access to relevant information (e.g., SOPs and performance metrics) for selection and oversight of service providers.
- 3.6.10 The sponsor should ensure appropriate oversight of important trial-related activities that are transferred to service providers and further subcontracted.

ICH E6 (R3) - draft

What does “adding value” look like?

What does adding value look like?



- KPIs lead to actionable insights
 - Focused on what is important
 - Purpose is clear
 - Definition is clear
 - People know how to use them
 - Context is provided

What is important?

- Past Performance?

- Selecting a vendor
- Planning future activity
- Benchmarking

- Future Performance?

- Monitoring risk
- Course correction
- Goal-oriented



Lagging

Leading

Lagging or Leading?

What questions are we trying to answer?

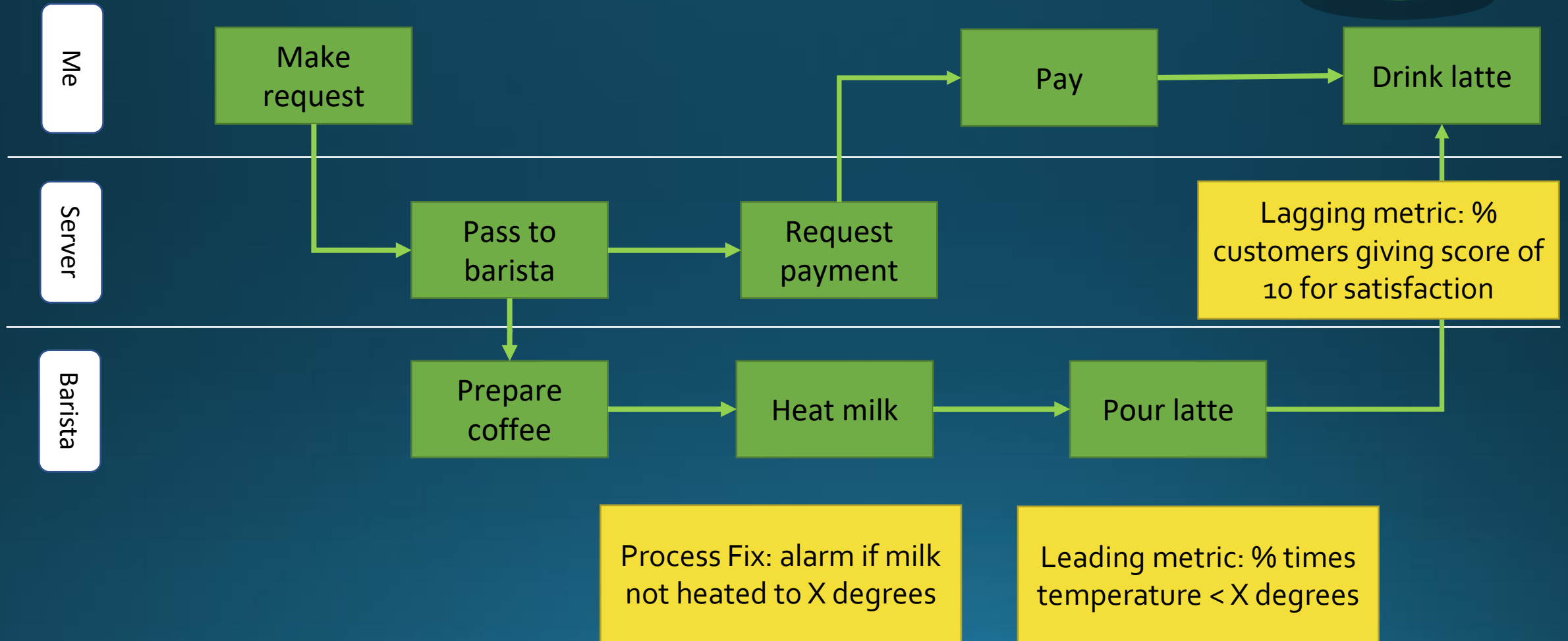
- Lagging: How did we do?
 - How long did it take?
 - How much resource did it take?
 - How often do we meet the target?
 - How many times do we need to review?
 - How often do we perform as planned?
- Leading: How are we doing?
 - How fast are we?
 - Are we using the expected level of resource?
 - Are we on track to reach our desired outcome?
 - Is our level of review so far as we expected?
 - Are there changes in expectations?

Measure when a process is completed

Measure when a process is running

Think Process...

“Urghh! My latte’s cold!”



Examples

- Lagging metrics

- Mean cycle time from draft to signed site contract
- % Database locks on time
- % actual cost vs original cost
- Average review cycles for monitoring visit reports

- Leading metrics

- % enrolment vs expected
- Screen fail rate
- Participant withdrawals per participant-month
- % hours this month compared with expected

What's in a name?

What's in a name

- Caution – the metric world is not binary!
- A metric can = KPI = KRI (= KQI)



Focus on the purpose of the metric rather than the name

Remember: Measure What Matters

Your KPIs should answer an **important question**
For example...

Are deliverables on time and to quality?

- % deliverables on time
- % deliverables right first time

How accurate are the cost estimates?

- % current planned budget compared with original expectation



Summary...

How can we use KPIs to add value?

- KPIs should lead to actionable insights
- Understand the purpose
- Leading and lagging metrics have their place – use the right type for your purpose
- Think process
- Don't overcomplicate e.g. metric, KPI, KRI, KQI

Questions?





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Keith's Question Corner

September 13th @ 12pm EDT, 5pm UK

Next Question: “Root Cause Analysis: Is Five Whys the best method?”

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