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Valerie Mulholland on Improving RBDM Effectiveness

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VALERIE MULHOLLAND ON IMPROVING RBDM EFFECTIVENESS

Editor's note: *This presentation write-up was prepared by the editorial team at International Pharmaceutical Quality (IPQ) and appeared in their publication "Implementing ICH Q9(R1) Will Entail a Heightened Focus on Integrating Knowledge into Risk-Based Decision-Making (Link: <https://ipq.org/implementing-ich-q9r1-will-entail-a-heightened-focus-on-knowledge-management-and-risk-based-decision-making/>).*



At the June 2023 PRST meeting on ICH Q9(R1), Valerie Mulholland, who is in the final stages of a PhD program at TU Dublin where the seminar was held and a PRST member, addressed: • risk management communication tools across history • human factors and decision complexity, and • insights gained through her research on the role of knowledge in improving risk-based decision-making. Click [here](#) for the slides accompanying Mulholland's remarks. Formatting changes and other minor edits have been made for clarity by IPQ. Expressions of thanks to the meeting organizers/attendees and disclaimers that the presentation represents the speaker's views and not necessarily those of their organization are not included.

I am doing a PhD here at Technological University Dublin on risk-based decision-making, and I hope I am nearly finished. I am going to share with you to-day some of the insights that I have developed through that process. I will talk about risk and knowledge and how they tie into decision-making.

Risk Management Communication Tools Across History

I wanted to show you this slightly incongruous slide first. What we are looking at here is a very ancient mariner's map that dates back to 1539. It is considered probably one of the oldest risk assessment documents known to man.

We are looking at the Nordic waters, with the south coast of Iceland off to the left and Denmark down to the right. The Dutchman who drew this drew sea monsters wherever there were hazards in the water.

It was a really clever way of communicating risk, because many of those ancient sailors had multiple languages and most of them probably didn't read, so it was a good way of communicating. And he illustrated what might happen if you met that sea monster as well – so very, very communicative.

But it was even more clever in that wherever the waters were uncharted – in other words, it was unknown what was in those waters – he illustrated that by dragons, and typically said 'Here be dragons.'

So straight away, in this map, he was communicating what was known about risk: where the hazards were, what was known about them, and what the consequences might be. But he also communicated what was unknown. 'Over here we do not know what we need to know.'

It is a clever way of communicating because I think we struggle with that concept even in our own modern risk management approaches – trying to distill into a document that communicates: ● what is known about the risks ● how uncertain we are about what we know, and then also ● what we don't know. And those challenges I think remain as real today as they were back then.

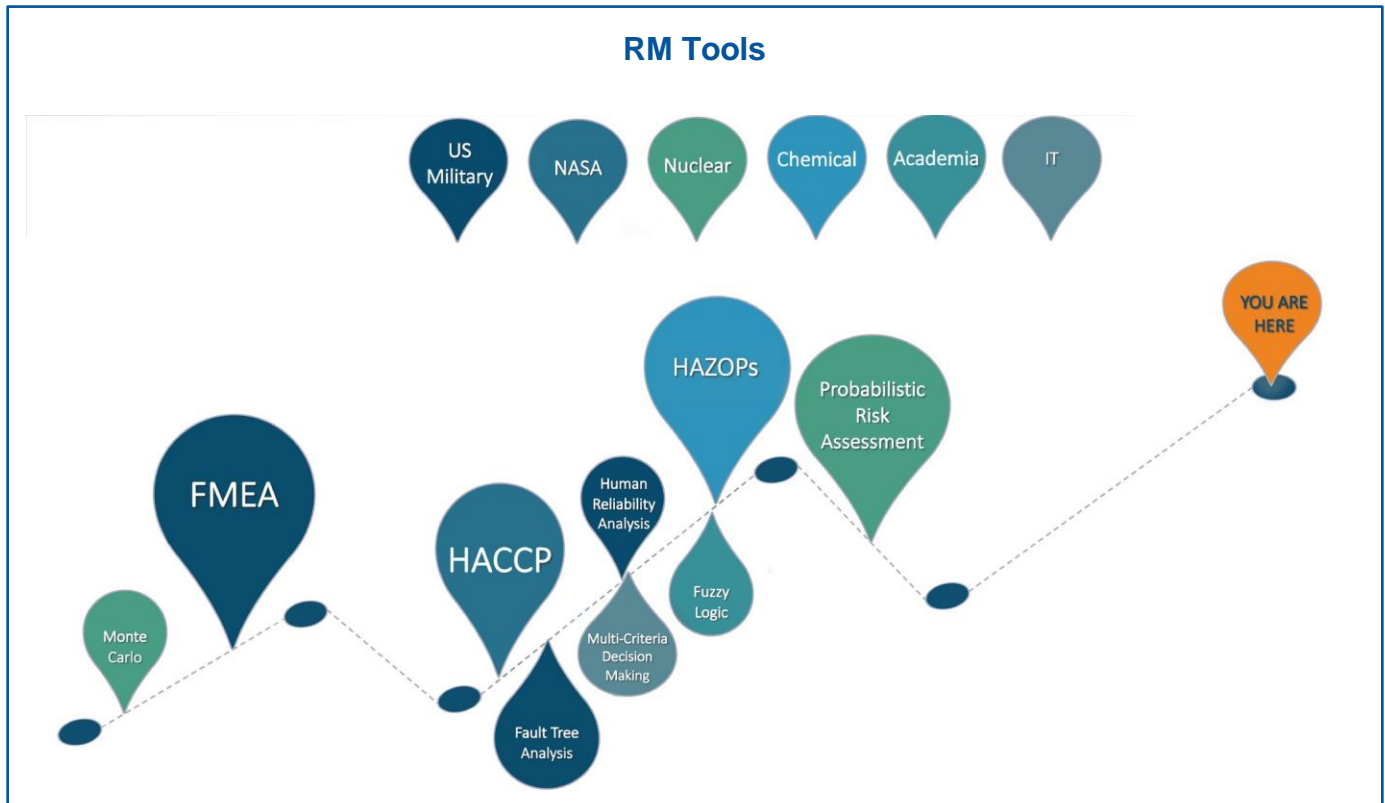
Risk Management Tools

Now, I would like to think we have moved on a bit from drawing monsters on maps at this point, and we have a range of risk assessment tools at our disposal.

I would just like to note, and I am going to do no more than note, that probably the one we most commonly use, let's face it, is the FMEA [failure modes and effects analysis], and it is one of the oldest tools in the toolkit.

It has served us well, and it continues to serve us well. But there are a range of tools, and maybe even more modern tools, that we could consider looking at as well. It has become such a 'go-to' that it is almost becoming a little bit worrying about the lack of utility and lack of consideration of the other tools.

One thing I want you to note as well is there seems to be a bit of a blank space here. I think this is something that Anders [Vinther] referred to this morning when he talked about Deming and what has happened in this area. There are new tools that have been developed but they probably have not trickled down to the common or garden risk assessment guys like us.



Computing Power and AI

But probably the big change that did happen was the whole computerization of all this – the horsepower that was gained by applying the power of computers to data collection and data analysis. Because that has been exponential if you like.

I suppose the next exponential leap we are going to encounter is, of course, AI. This is just going to go quantum when you start using the power of things like Chat GPT to collect the data, to analyze the data, but then to gather the insights on the data – which used to be our ground, right? That is going to cause major disruption and major change.

I think it was 2015 when artificial intelligence overtook the intelligence of mammalian species. Okay, that was the mouse, but by 2030, it is anticipated that it will overtake us as the human brain. And I think by 2045 they reckon AI will be more powerful than all human brains combined. It is a bit scary, and I think there are some here who remember HAL in "2001: A Space Odyssey."

Human Factors and Decision Complexity

The reason I point all this out is because I think it is true to say that maybe we are becoming the rate-limiting step here. Apparently, the human brain has gotten five times smarter in the last 4 million years.

So our capacity and capability to make decisions is quite primitive if you like, and designed to make different types of decisions – ‘there is a buffalo charging at me’ type of decisions. And so our decision-making capabilities rely an awful lot on instinct and on intuition. We are designed to make quick decisions rather than accurate decisions. That is just the way we are designed.

This morning, we heard people talking about biases, subjectivity, and heuristics. It is hard to get rid of them because they are kind of hardwired into our brains.

And modern man does not have it easy either. Modern man is overwhelmed with the amount of information we have. I think most of us have bosses who just want to see it all reduced to a dashboard or a graph or a chart or a pie chart or what have you. We reduce our information for the decision-makers, and the problem is in that reduction, we may lose those insights. We may lose our ability to apply that human judgment to it. That is worrying as well.

When you add to this that our problems are becoming more complex, the complexity of the problems is somewhat overwhelming, and the ability to manage and make judgments on a large amount of data is overwhelming. And then we have all sorts of indiscipline in our brain, where we get very fed up very quickly if the decision seems too hard or too information-overloaded.

We are equally poor at the other end with probabilities. I think once you are above a probability of more than one in a hundred, we just cannot see it.

Decision Complexity and Wicked Problems

So we are a rate-limiting step in all of this. And this is particularly true, as I am trying to say, when you meet really complex problems. We mentioned complexity as being a factor in all this several times this morning.

And so, it is worth taking a moment to look at the scale or complexity of problems, and therefore the complexity of the decision-making that supports those problems.

Down at this end, to be honest, most of the problems we would meet in our operations on a day-to-day basis are probably what we call **‘tame’ problems [see below]**. Now, that does not mean they are simple problems – don’t confuse those terms.

But it does mean that the problem that meets the characteristics here is probably easy enough to articulate to get a problem statement together. It is possible to gather information, gather knowledge, and evaluate it to understand the risks and to come up with a solution to the problem. And when you apply the solution, you probably pretty quickly know whether you made the right or wrong decision. These are well-structured processes.

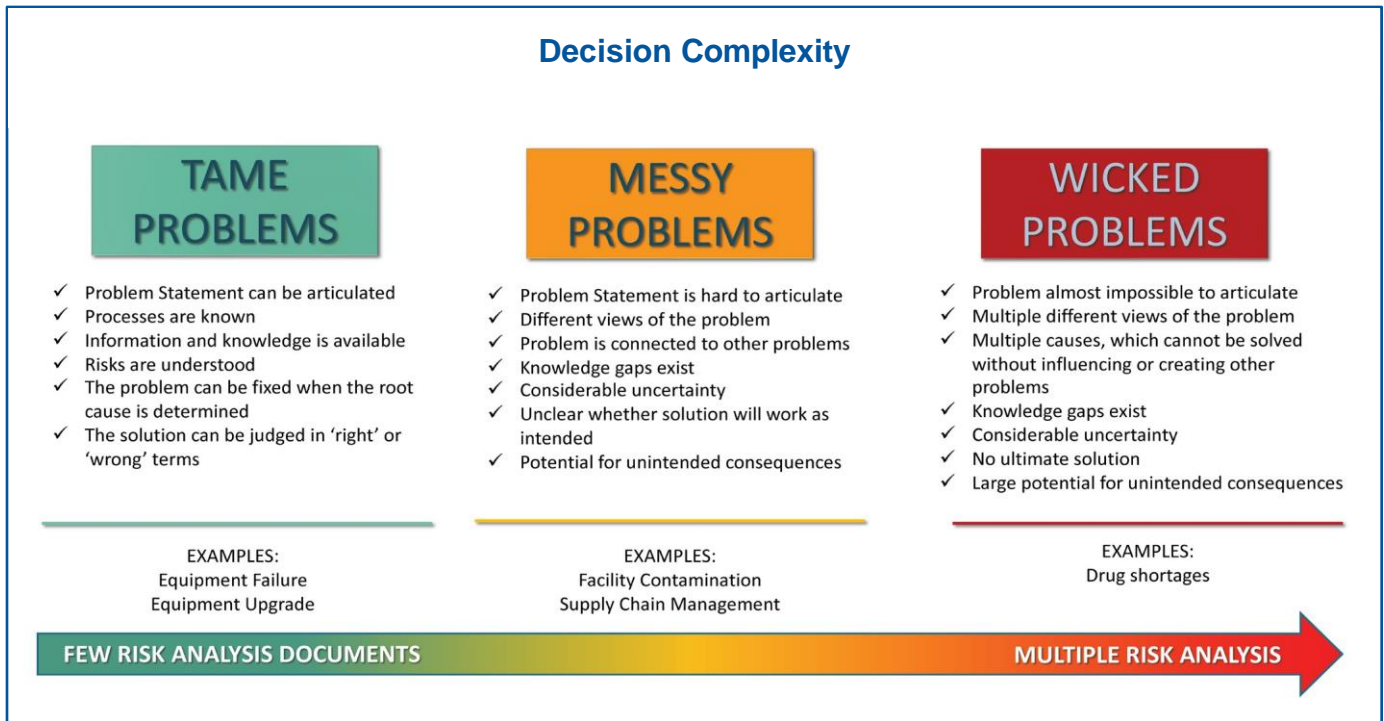
On the other end of the scale though, things get messy, and things get wicked in fact. And what we mean here is that the problem statement may be hard to articulate. And there may be several problems in there. Different people have different views of the problem. Different people think the problem is a different problem. There are gaps in the information, leading to a lot of uncertainty. It is unclear whether the solution you come up with will work as intended.

Over here at the **wicked** end, it is quite likely any solution will impact another aspect of the problem. And it is hard to come up with a solution for one without disrupting something else. So you have got all these interdependencies, complexities, interrelationships and at the wicked end as well, the problem is probably running ahead of you, if you know what I mean. As soon as you understand it, it gets worse the longer it takes you to figure it out.

And when you start talking about these types of problems, drug shortages are probably out at that end of the scale. I think Anders and Emma [Ramnarine] have actually called the drug shortage problem a wicked problem. There are so many stakeholders, and so many moving, interconnected parts involved.

These types of problems probably involve multiple risk analyses. It is not a matter of looking at one document. You are looking at several documents and weighing up many, many things. And you are trying to figure out risks and benefits and trade-offs. There is a lot of complexity of thought here.

We need to start perhaps putting a little bit more structure on the process to guide us through those complex situations and complex processes.



Research Insights

I am going to share with you four insights from my work today, which I am hoping will be takeaways from this session for you.

(1) The Need for Complex Decision-Making Processes

The first is to appreciate that complex problems may need complex decision-making support and complex structure in terms of how you approach the decisions. And those of you who have heard me talk before will know one of the first things I did in my work was prompted by the concept paper that Kevin [O'Donnell] mentioned earlier, which said there are many industries out there that are dealing with high-risk decisions – how do they go about it?

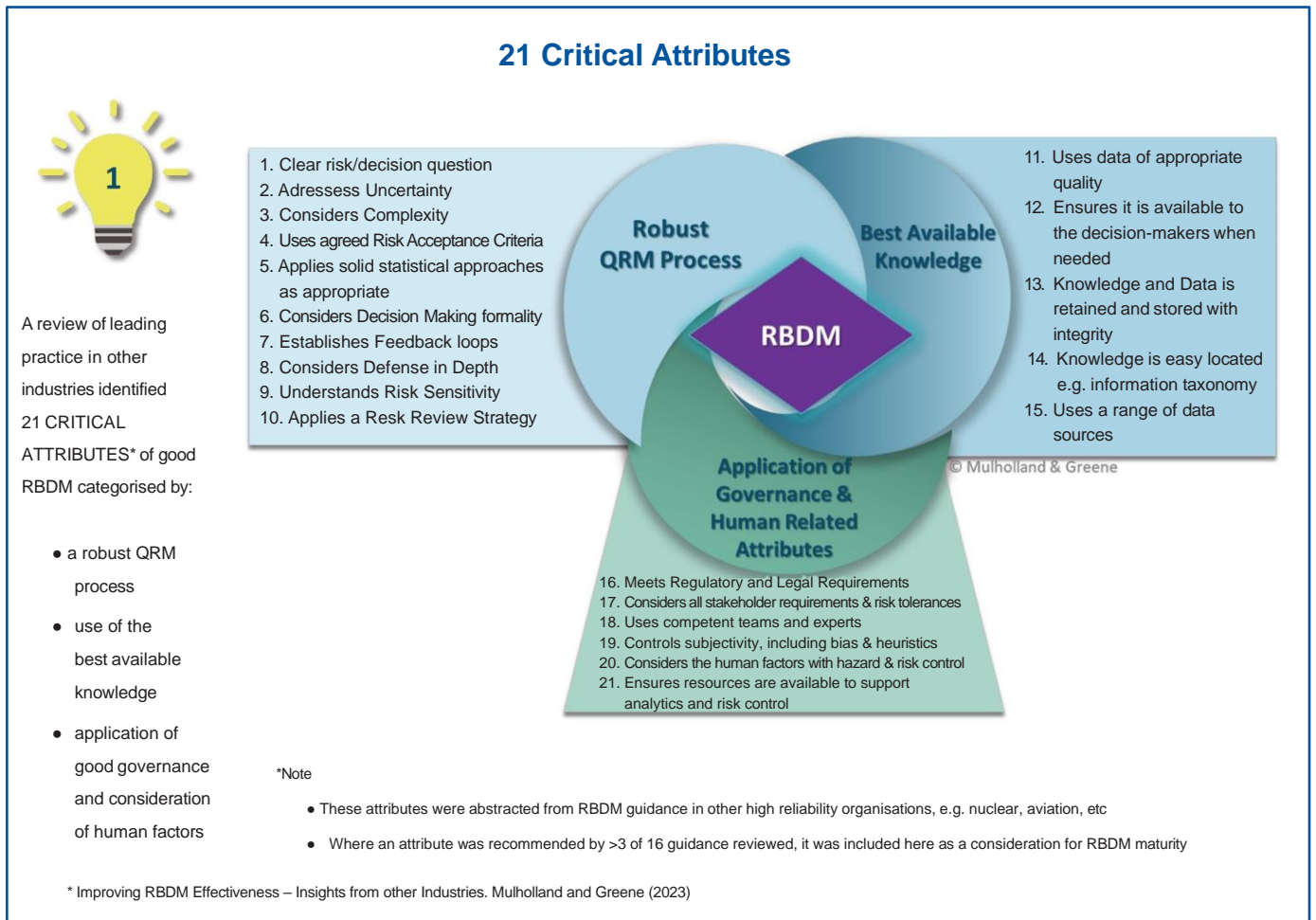
So, I gathered up every manual on risk-based decision-making from every high-risk industry I could find, and I came up with 21 attributes of critical risk-based decision-making. Now this doesn't mean you have to pull all 21 of those attributes out every time at all. But when you are out at the wicked end of the problem, every single one will become very, very useful.

And I think we do have to recognize that there are a lot of factors that need to be considered here. You will notice that about 10 of them are related to having a good quality risk management system.

A further five though, recommend knowledge management – various aspects of making sure knowledge is available to that decision maker. And that really is, as Michael [Schousboe] said, why ICH Q9(R1) places such an emphasis on that.

The other five are around governance and human factors, and that recognition that we are prone to shortcuts. A very good read here actually is Daniel Kahneman's 'Thinking, Fast and Slow.' It is a really good book in terms of explaining how our brain takes shortcuts, particularly when we are stressed.

So controlling those human factors, those biases, those heuristics, those subjectivities is part of these 21 characteristics as well.



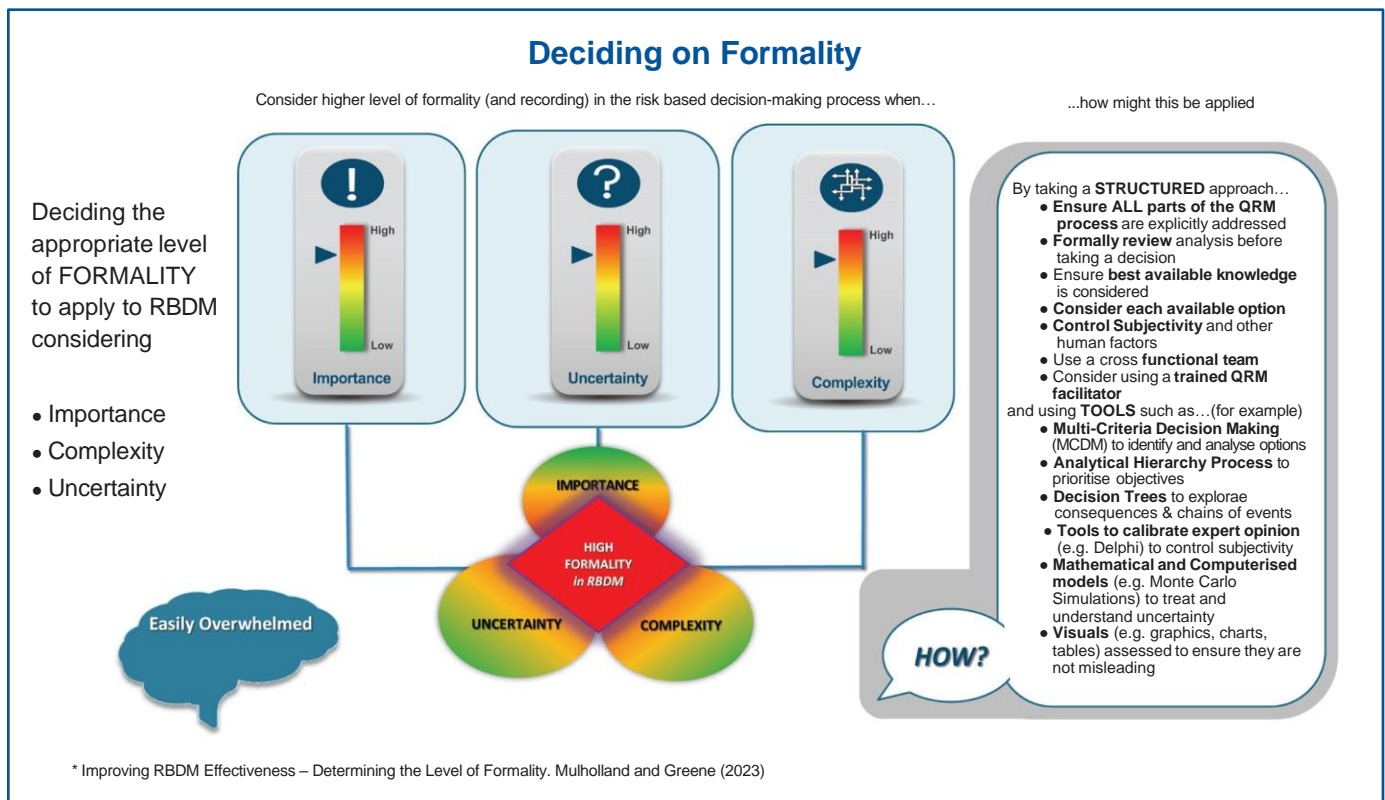
Bringing it back to our situation and looking at these highly complex problems – and again, referring to the fact that this idea of complexity is a continuum – what are we talking about here on a practical level?

I suppose we are talking about taking a **structured approach**. And to be fair, ICH Q9(R1) guides us through what that structured approach might look like. It says to make sure you go through each step in the process, and don't be shortcutting – your brain is shortcutting, as it is. Shortcut through the process and you lose the discipline of that process.

Make sure you get the best information available. Consider all the options. Control subjectivity – and it was a good question this morning about how you do that when you have lots of voices. If you want to read Gregg [Claycamp]'s work on that, you will get lots of advice there.

There are **tools** we can use to discipline ourselves: • multi-criteria decision-making • arranging things in hierarchies of priorities • decision trees • tools to calibrate expert opinion, and • we need to become more familiar with mathematical models and computerized models. We need to be more comfortable in those spaces.

FMEA is kind of a one-factor-at-a-time type of guy. It doesn't work very well for us out at the complex end of the problems. Complex problems will require complex computations. We need to get comfortable with understanding what those models mean, and what they are trying to communicate to us. And we need to make sure we understand visuals and graphics and charts and pie-charts that are put in front of us so that we can interrogate those for the uncertainties and the dragons that may lie within them.



(2) Providing the Best Available Knowledge About Risk

Knowledge is one of the words of advice here. So this is my next piece of advice: make sure you have the best available knowledge.

Those of you who are familiar with the work of PRST may have seen my colleague, Dr. Marty Lipa's work on this interconnecting knowledge and risk – whereas knowledge is an informatic into quality risk management, and from quality risk management, we also gain more knowledge. **[See slide #10.]**

This is particularly important to you when you have very long lifecycles. Our products have long 15-20-year lifecycles. Maintaining that knowledge and transporting that knowledge through that lifecycle is a body of work and does require a management system.

Let me just explain, in terms of decision-making, what I mean by knowledge. Again, I think this was mentioned a couple of times this morning, the DIKW [data, information, knowledge, wisdom, decisions] pyramid.

At the bottom we have data. Data means nothing without context, without it being organized. Once it is organized, we tend to call it information. Then from that information, we need to extract some meaning. And it is that extraction of meaning that we are talking about when we use that word 'knowledge.'

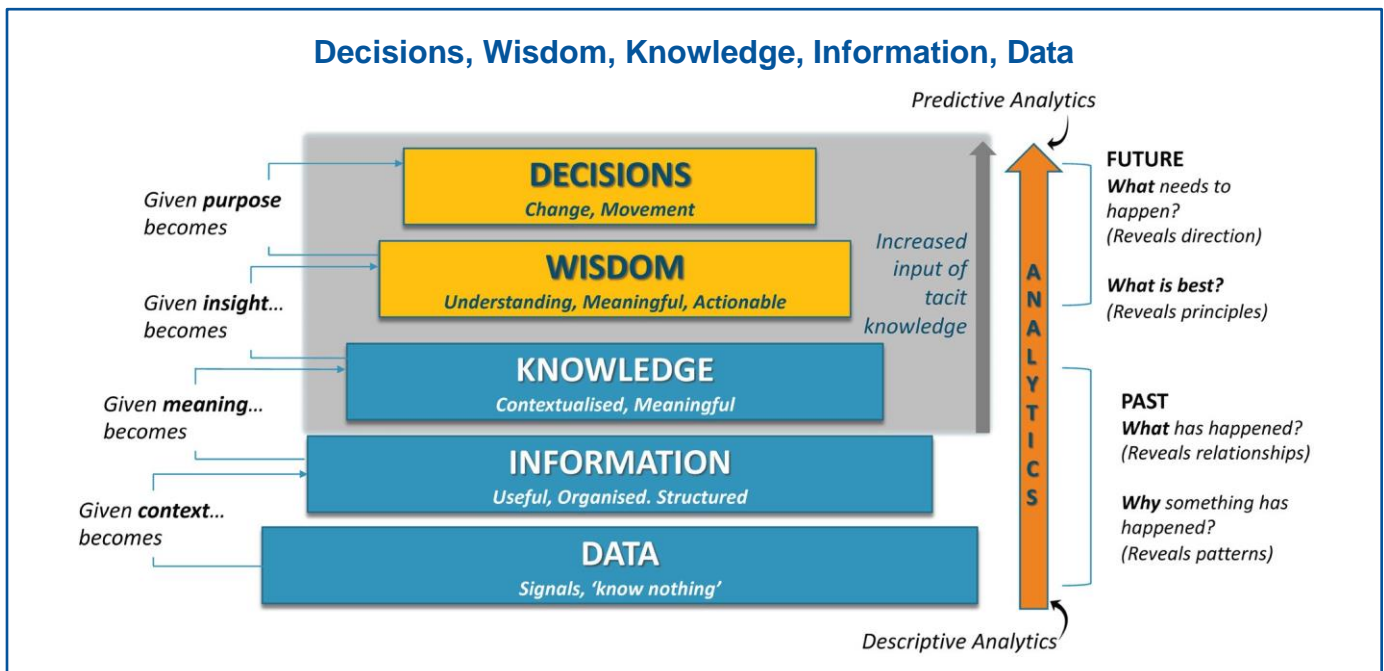
Hopefully, then we will go further up the ladder, and from all that knowledge and experience and information, you will get that sense of wisdom – knowing how to apply it and when to apply it. Knowing when it is relevant and when to call on it in order to be able to inform your decision-making.

The reason I use two colors is these blue blocks are kind of from the past. This is us using the information we have in the past to understand what has happened. Why did that happen? Why is it relevant? And to extract that meaning.

The orange blocks then are looking to the future. How do we use that information to be better, to get better, to improve our operations? What needs to happen in the future? What is the best way forward? And this is where people factors come in at the top of that pyramid.

And as we go up this pyramid, the type of analytics varies as well. So down here, we are analyzing things that have happened. We are analyzing real data, real evidence. That requires what we call descriptive analytics.

But the further we go up to try and predict what that means in the future, we are starting to use what is called predictive analytics. And of course, the more you call it, the closer you go to prediction maybe, and the more uncertainty is involved as well.



(3) The Impact of Limited Knowledge

Now what happens when you have very little knowledge? The pyramid kind of shrinks like this. **[See slide #12.]**

Now you have a gap in terms of the wisdom for going forward. And now we really have to rely on those predictive analytical models. Let us ask ourselves, is FMEA the best tool for that? Or are things like probabilistic risk assessments or other more modern tools more helpful in terms of understanding the uncertainty that may be associated with that prediction going forward?

This is the environment we have to learn to work in. Because Emma and many speakers this morning were talking about innovation. If we want to innovate and improve, we have got to learn to make good decisions with less information. By the time we wait until we have all the data collected, too much time has gone past.

Sometimes we find ourselves in situations where we have limited knowledge, and therefore we have high uncertainty. Route one to solve that would be to gather more information and gather more knowledge – to wait.

This is an adaptation we have made of Marty's loop **[slide #13]**. Substantial knowledge should reduce uncertainty. But you know, we don't always have the luxury of that, right?

Or we can plan it better. Let us go back to an FMEA because it is what we are familiar with. When we score something high – meaning this has the potential to be severe – when we continue to do our QRM in terms of likelihood and all that, we could also be thinking about what knowledge we need.

So let us now pretend that even if we are scoring this as a low likelihood of occurrence, it is a high-impact, highly disruptive, very unwanted event. We should start to think about what information and knowledge the decision-maker needs in the event that it should happen. **[See slide #14.]**

I was just looking at Michael's example about the calibration intervals, where he said, 'We needed all this information to make the decision.'

Layer on to the basic risk assessment, the added concept that if this calibration point were to fail in the future, for sure we would perform an investigation, but someone has to decide on the impact of the calibration failure on the product produced. And what information does that person need to make that decision?

There are very few decisions in our operations that don't have a prediction factor, and it is just a matter of predicting that while we are there.

When you are in this realm of prediction, when you are out at this end of the spectrum with high uncertainty, it is a different thought process as well. So over here, we do what is called deductive reasoning. We are using data, and we are looking at information. We are trying to understand it and analyze it.

But when we are looking at predictive analytics, we use what is called inductive reasoning. We are inferring from the data what the future might look like. And that requires a different skill set – not one that we are well-practiced in. It requires a high level of maths, numeracy, statistics, statistical thinking, all the things we were yawning about this morning. But they matter when we are trying to predict the future.

(4) Decision Review Across QRM Process

The final thing just to say is – and this was mentioned this morning – to gain a skill you need to review it. We were talking about risk review. Kevin mentioned it a couple of times.

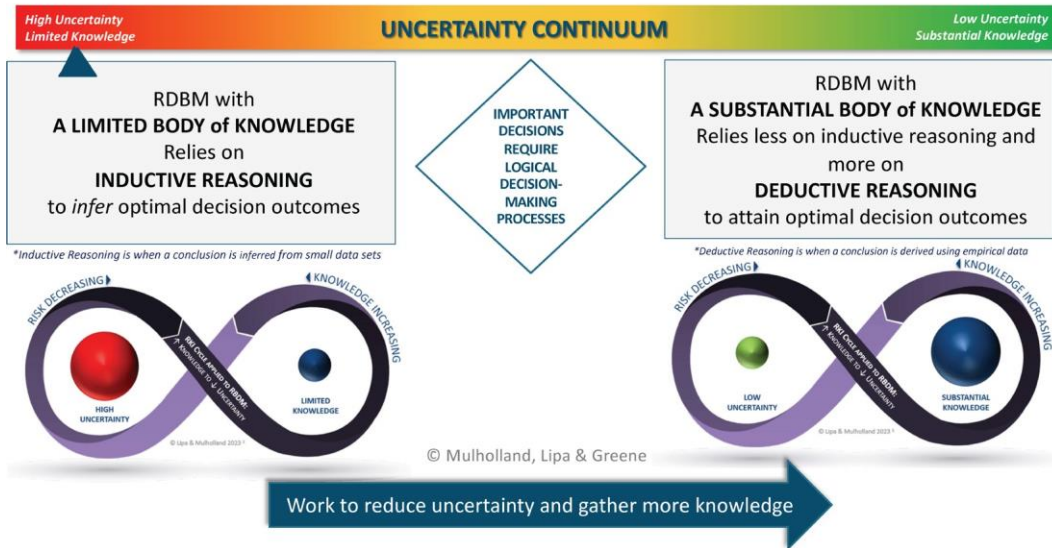
I am also suggesting that we should review our decision-making as well. Not just the risk but review the decisions that we make. We are not going to get any better at decision-making unless we put in some model that asks us to look back at the decisions we have made and the difficulties we ran into – that lessons-learned concept that NASA does.

Did we have the right information? Did we have the right people in the room? We cannot fix it now, but we can fix it going forward.

Decision Making Under Uncertainty

Depending on the extent of the body of knowledge different REASONING is required.

What does one do if a decision is **IMPORTANT** and/or **COMPLEX** and the risk understanding is **UNCERTAIN**?
(i.e., when there is a lack of knowledge)



* Improving RDBM Effectiveness – Addressing Uncertainty. Mulholland, Greene and Lipa (2023)

So if we want to improve our decision-making, maybe we should introduce these key decision review points. These are not decision points. They are key decision review points at stage gates. **[See slide #18.]**

There is a paper to support each one of these slides and it is available on the PRST website. Everything I said here has been academically researched, so there is no need to be drawing monsters on maps anymore, just four practical things to introduce. There are 17 more if you are interested, so watch the PRST space.

Risk Based Decision-Making

1. Appreciate that complex problems need complex decision-making processes

2. Provide the best available knowledge about risk

3. If knowledge is limited, different reasoning is required

4. Review RDBM throughout the QRM process

THANK YOU
(There are 17 more, if you are interested!)

With thanks to Prof Anne Greene & Dr Lipa

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