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Risk-Based Regulation: What We Were Doing All Along and What We'll Do Differently in the Future

Risk-based regulation vs rule-based regulation can be summarized in a story of driving over a deserted bridge in Canada at 2 a.m. The speed limit is 40 kilometers per hour (kph). But it's a long bridge, the sky is clear, the roadway is dry, and you just want to get home. It would be perfectly safe to drive 50 kph, so you do, until you see the flashing red lights behind you.

The officer is practicing rule-based regulation. If the officer had been searching out drug dealers in the dead of night instead of strictly enforcing a speed limit that doesn't apply to the conditions, he'd be practicing risk-based regulation.

A key feature in a vision statement for risk-based regulation would be the idea of the proactive prevention of harms.

Risk-based regulation is being practiced to varying degrees at the College of Physiotherapists of Ontario and the College of Physical Therapists of British Columbia.

Risk-based Regulation is about a New Way of Thinking
There's never enough time and money to prevent every single harm. And that leads to the real selling point of risk-based regulation: it's a mechanism to figure out what the riskiest activities are and focus your resources on those.

It's different than the old way of regulating. It's different than the cop on the bridge. Ontario has many rules. Regulators work hard to ensure they're clear and fair. The risk focus asks regulators to think less about the rule-making and to be nimbler, to set the rules aside and instead see where the harm is about to happen and go there and stop it before it occurs. The 40 kph limit is based on some evidence, perhaps because that's the safe maximum speed under average conditions. But in the middle of the night and it's dry and it's summer and there is nothing else on the bridge, that's not a reasonable rule. Perhaps the rule had been set at 40 kph before car brakes were as good as they are today. Maybe it used to make sense, but today it doesn't need to be that low. Or maybe the speed limit is irrelevant because, in fact, cars driving fast don't cause as many accidents as distracted drivers who

are spending their time texting while they drive.

The alternative is to figure out what's causing the harm and go right to that place. Perhaps the police don't consider the speed limit at all at 3:00 on a Saturday morning. The risk is more likely to be drunk drivers, so they figure out a way to screen for drunk drivers. In every big city, it's a very slow drive during the morning commute, and everybody is texting work to say they're going to be late. So, instead of worrying about the speed limit, maybe the police will look at who's holding a cell phone. That would be risk-based because they'd be looking for the real cause of harm instead of looking at the rules.

The problem for regulators is they don't have the authority to go in and fix a lot of things regulators believe are broken. For example, no jurisdiction in Canada regulates physical therapist assistants. Canada also doesn't regulate the clinic setting. So, much of the harm comes from a non-regulated owner who's running a crappy organization using lots of under-trained, unregulated assistants to deliver substandard care. A risk-based regulator would try to fix that system's problem. But Canadian regulators don't have the jurisdiction to do that and are not allowed to do it by law. That's the barrier to risk-based regulation in some settings.

Risk-based Regulation Carries Many Benefits

It might be worth fighting for, because champions of risk-based regulation make a really strong case. The Guidance for Regulators for Outcomes and Risk-Based Regulation was published by the South Wales government in 2015. It lists several benefits of risk-based regulation.

- Better alignment of strategic and operational planning — aligning the regulator with cluster, department and state priorities contributes to more effective government
- More effective engagement with internal and external stakeholders by demonstrating how regulatory initiatives impact outcomes
- Improved internal accountabilities for outcomes through embedding the framework into strategic planning and performance management
- Greater flexibility through improved information to respond to changing circumstances
- Improved productivity through better understanding efficiency and effectiveness, enabling more informed financial and human resource allocation

Greater flexibility would help in College of Physiotherapists of Ontario. For example, the college is required to complete investigations within 120 days, including every silly complaint.

Someone could complain about the wallpaper in a physical therapist's office and it would have to be investigated and taken to the screening committee. Even if the most superficial investigation is conducted, the complaint must be to a committee of five busy people, and it costs money. There are sexual abuse cases out there. In a sensible world, it would make sense for regulators to have the flexibility to put the wallpaper case on the shelf for 56 years so they can deal with the things that are causing patients harm. Regulators need to be Spider-Man, using their Spidey sense to go to the place where they know the bad thing is about to happen and fix that thing.

Change is always difficult, but perhaps the shift from rules-based to risk-based regulation is

particularly challenging in that it requires both energy and creativity, and maybe a little political force, because there are things about this that keep regulators inside their box. The regulatory agency starts by collecting information in a systematic manner, then uses it to identify hotspots. The information will then be used to inform the regulator's Spidey sense to figure out where the hotspot is, what can done about it, and what the regulatory response should be.

It's All in the Data

The College of Physiotherapists of Ontario uses the Program for International Student Assessment (PISA) self-assessment and other tests that are part of its quality assurance program. It has practice advisors who are available to answer calls and emails, and soon possibly texts, from members of the public or from PTs who want advice. The college tracks the nature of the complaints and reports what it gets, what it is about, who it is from, the region, and other data. Open rates and click-through rates are analyzed, as is how much time people spend on what pages on its website. The data is used to adjust the educational and communication efforts.

Ontario retains its registration fees and therefore has the funds to execute its data analysis. Ontario's board uses it to inform strategy and its committee decision-making. The board is the policy decision-maker, in addition to a screening committee and a discipline committee: three different entities doing the job of one U.S. board.

An example of how the data is collected and used comes from the practice and advice (PA) team. The PA team keeps records of the nature and frequency of the calls they receive. When they start to notice a trend, they bring it forward to the senior management team, which does an environmental scan to try to figure out the cause of the trend. Did they just publish a new policy or standard? Did the rules for payment change? Did a new insurance company come in? And are they doing something differently? Figuring out the cause of the trend tells Ontario what problem there is to solve. If many people start calling for advice about one issue, there is a problem to solve. Then the challenge is to figure out what regulatory tool would be best to solve it.

For example, Ontario experienced a sudden surge in calls about supervision of assistants. It was tracked to publishing a new standard for supervision that introduced some more rigorous requirements. And the fix, based on the nature of the inquiries, was more education. The team created a YouTube video, published more educational materials, and it became the focus of Ontario's social media communications effort.

The ability to identify what's the real locus of potential harm and what is the public policy, the clear public policy justification for spending all your money and efforts there, is a critical factor to risk-based regulation.

Another example demonstrates Ontario's efforts to do that. ICRC is its screening committee, and all complaints are looked at by the ICRC. Over the past several years there has been a tsunami of concerns about fraud, waste, and abuse. The screening committee begins to see those concerns are becoming a higher and higher percentage of the matters they're dealing with. And they kick it back to the board at strategic planning time, to say, "Hey, board, this is a very important environmental trend that you should be thinking about addressing." And the board then builds that as a focus, one of three strategic goals for the coming five years. From there, tactics are developed. One of the tactics the board approved was creating a

zero-tolerance statement. It then is used in the organization's education and communication efforts.

It also is built into the screening risk assessment tool used by that screening committee to decide whether further action is warranted. It's used by the discipline committee to think about what kind of penalties to make. It's used in the stakeholder relations materials to persuade those payers the organization is serious and are partners in curbing this problem. As a result, there is an increase in the number of referrals from the screening committee to the discipline committee. The discipline committee issues harsher penalties. And insurance companies increasingly send information about fraud, because they know the regulators take the information seriously and do something with it. There is a translation from data, to action, to outcome.

What's the Risk?

Problems that come to the regulator's attention can be grouped into four levels of risk: None, low, moderate, and high. When a minimal or no-risk complaint or matter comes to the committee, there should be no action. A high-risk matter requires action, up to a referral to discipline. Ontario now has the power of interim orders, so if it's a particularly egregious high-risk case, the committee can suspend the person's license immediately. It depends on the PT's discipline history and the circumstances in which the behavior occurred.

Those outcomes are publicly available on Ontario's website. It doesn't matter what the nature of the complaint was. If it's deemed to be a moderate or high-risk to the public, then everything about that individual's complaint, except the complainant's name, is posted on the website.

Data does not quantify the harm to patients. Maybe there isn't a need for the evidence to say sexual abuse of a patient is always harmful and should be considered high risk or that complaints about advertising should be low risk. Although the agency receives a fair number of complaints, usually from competitors, and it has a standard about advertising practices, it seems that in today's informed marketplace it's doubtful the breach of the advertising standard causes a great deal of harm. It's a gut feeling that says people are going to Yelp and they're going to rate their PT, and they're looking at each other's blogs, and there are lots of ways for people to assess the veracity of the advertisements without the agency spending time and money on it.

Regulators in the healthcare field also need to look at desired outcomes and their public value. If more bicyclists are suffering brain injuries because of poorly designed bike helmets as opposed to poor materials used to construct them, risk-based regulations would dictate regulators look at helmet design as a way to keep the most people safe from injury. But some people are still going to get hurt because of poor materials. Regulators need to decide what the right thing to do is from the perspective of the highest public value.

The public regulators serve needs to believe in them. In the mid-2000s in England, objective evidence pointed to more people being harmed by a lack of hospital beds than by hospital-acquired infections. But which one of those is scarier to the public? While the policy wonks attempted to spend their budget on increasing the number of hospital beds, the politicians decided to spend it on deep-cleaning every hospital because that's what they perceived stakeholders wanted.

Another problem with risk-based regulation is that no one can assess the consequences of the undesirable behavior. Again in England, Mid Staffordshire Trust was a hospital that imploded with astonishing death rates. The regulator had been using a sophisticated risk-assessment matrix based on the probability that the providers would breach standards. Yet, when they investigated, they found that every process was flawed. They thought they had it right. But they were looking in the wrong place. It's difficult for a healthcare regulator to determine where to look and know what to do next.

Does that mean risk-based regulation is impossible for healthcare? Perhaps. But there are many valuable areas of focus that regulators can take from this philosophy.

Continuing Competence is Part of the Mix

The College of Physical Therapists of British Columbia has a quality assurance program, or a continuing competence program. The BC program was developed jointly with the College of Occupational Therapists of British Columbia. The colleges shared the consultants used to develop the framework, the technology platform, the psychometricians who do the analysis, and the learnings.

BC has had a quality assurance program since 2008. The purpose of it is to monitor and support the continuing competence of physical therapists in British Columbia. It's a legislative requirement, although the methods they are required to use are flexible. Any program will do as long as it gets at the heart of continuing competence. BC now has nine years of data from its program.

Early on, BC worked with Dr. Susan Glover Takahashi. Takahashi is a PT who spent much of her career working in the area of competence. She works in the Faculty of Medicine at the University of Toronto and she has a particular interest in what she refers to as the epidemiology of competence. She's done lots of research looking at patterns, causes, and effects to understand risks related to competence, particularly in medicine. And she's also very interested in looking at how you modify them, how you manage them, how you prevent them, and what interventions make a difference to improve the competence of practitioners. The colleges hired Takahashi and her team early on to help develop the conceptual framework for this program, and then Takahashi worked with the colleges for several years in doing the foundational work that led to the program.

Takahashi had done a lot of work in terms of reviewing literature, particularly in medicine, before BC started working with her. She did another literature review in 2007 that was delivered to BC. And from that, the colleges learned three key things about the area of risks and supports in competence. The first was that the literature did identify the most frequently identified risks and supports to competence. Second, the reasons for the risks are not particularly well understood, which still applies today. Regulators know what they are, both on the risks and support side, but not particularly why they exist. And, third, the strength of association is not established in the literature, so risk-to-risk or risk-to-competence are not particularly well-established.

BC chose to develop an approach that prioritized registrant education and engagement. The thinking was that by raising the awareness in the physical therapy population about risks, and mitigating those known potential risks, that it would add value to the profession. That really became the focus of this program. And the colleges developed a tool called the annual self-report, and it is focused on potential risks and known supports. It's a tool that

registrants complete themselves. The colleges are careful to articulate to their members that there is no evidence that the presence of a potential risk equals harm, or equals any kind of incompetence.

There are three components to the quality assurance program. Competence maintenance is the bucket that the annual self-report is in. Competence assessment includes a registrant competence assessment, which is a screening examination. It is the most controversial component of any quality assurance program in Canada. And then, there are other assessment and remediation pieces if registrants are unsuccessful in the screening.

The annual self-report is completed online and administered by a third party. It includes 23 questions. Eleven are questions to identify a physical therapist's potential risks and supports to competence. One is about the registrant as a practitioner, and the other is about the practitioner's practice. That makes up the first section. And then the second section is 12, self-quiz, case-based questions that assess a registrant's ability to apply regulation in practice. It's kind of like a jurisprudence examination, and it is developed on an annual basis and reflects issues BC uncovers in its Practice Advice Program.

Those issues tend to be under the overall questions of consent, professional boundaries, therapeutic relationships, clinical record-keeping, privacy, and confidentiality. Then the registrant receives individualized results in a report immediately upon completing it. The "report has been prepared for you and includes an inventory of potential risks and supports to your competence as a physical therapist," it states. "Remember, these risks are not indicators of incompetence but are potential risks to your competence, like risks to your heart health, high blood pressure, overweight, family history. Some are modifiable and some are not. Risks should not be viewed as judgments of your competence nor as evidence that you have problems. Risks are important factors that the college wants to make you aware of, and where possible, and you view important, take measures to manage your risks."

And then it goes on through each question and indicates, "Was this a risk for you or not? And here are some of the supports that you might put in place." All registrants must complete the self-assessment. Registrants include full registrants, who would be a registrant with no restrictions, and interims, who haven't completed all of BC's examination process. There are also non-practicing and student registrants. All the full and interim registrants, those people who are actually in practice, must complete it. It's done annually and it's done just before the registration renewal. It is a requirement of renewal of a license to practice. BC recently finished the 2017 administration in time for its 2018 renewal year, and that will give them their ninth year of data.

Test Reveals Risks and Supports

Transitions are a significant risk in the literature, whether that be personal or professional. Because of that, a question like this may be asked: "Returning to an act of practice after a period of inactivity can affect your risk of competence in patient care. This year, did your registration status move from inactive to active?" The OTs have chosen to focus significantly on transitions in their practice. They found the people who end up in a remediation tend to have had very significant transitions in their life, whether that be illness or changes in their work life. If someone admits to a significant transition, the report might state, "Make sure you develop a re-entry plan, including learning new protocols, best practices, and employer-related policies and practices."

According to the literature, males are guaranteed to have more risks in their practices than females. Age, particularly 70-plus, is a factor, as is being foreign-educated. Another potential risk is a low score on the entry-to-practice exam. History of complaints, adherence to deadlines, and working in isolation, also are potential risks.

Potential supports found regularly in the literature include participation in continuing education, support by either a practitioner's employer or others for continuing education, access to educational information and resources, membership in professional associations, mentoring students or others, annual performance reviews, participation in a quality assurance process related to their practice, and connection to other physical therapists or healthcare team members.

The benefits are that physical therapists can monitor their own potential risks and supports. They are supported to understand the laws and regulation under which they work. They're given suggestions for how they can mitigate some of their risks, and they can monitor their own continuing competence around regulatory topics. It helps regulators monitor registrant understanding of regulation and their potential risks. It also provides aggregate data for the agency.

BC has never had anyone who's reported more than five risks. The average is usually one. It's a fairly low number. In terms of the supports, these tend to be fairly stable at five to six. There is a lot of support for continuing professional development and continuing education activities. At the bottom, at 27%, is performance review in the last year. That's a significant problem in the Canadian healthcare environment, in the public sector in particular. Someone can work there their entire career and never have a performance review.

BC monitors the results for trends, potential risks, and supports. Results also inform the regulators' interactions with registrants. It helps identify education and communication needs. BC contemplates innovative ways they can communicate information to their registrants so they can help support them in their competence efforts. It also helps BC to refine questions year over year. Every year BC conducts a forum with PTs, and much of the information derived from the aggregate results are presented back to them.

In the future, BC would like to look at correlations. It wants to provide members with more detailed strategies to help them mitigate risks. BC is interested in learning if there are relationships between risks and performance on certain topics in the case-based questions. They also would like to see how they can provide information back to the physical therapists that's more relevant, such as a five-year data trend report. BC is in discussions with Australia, which is very interested in the assessment test. It would be fabulous to do it across continents and compare data.

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