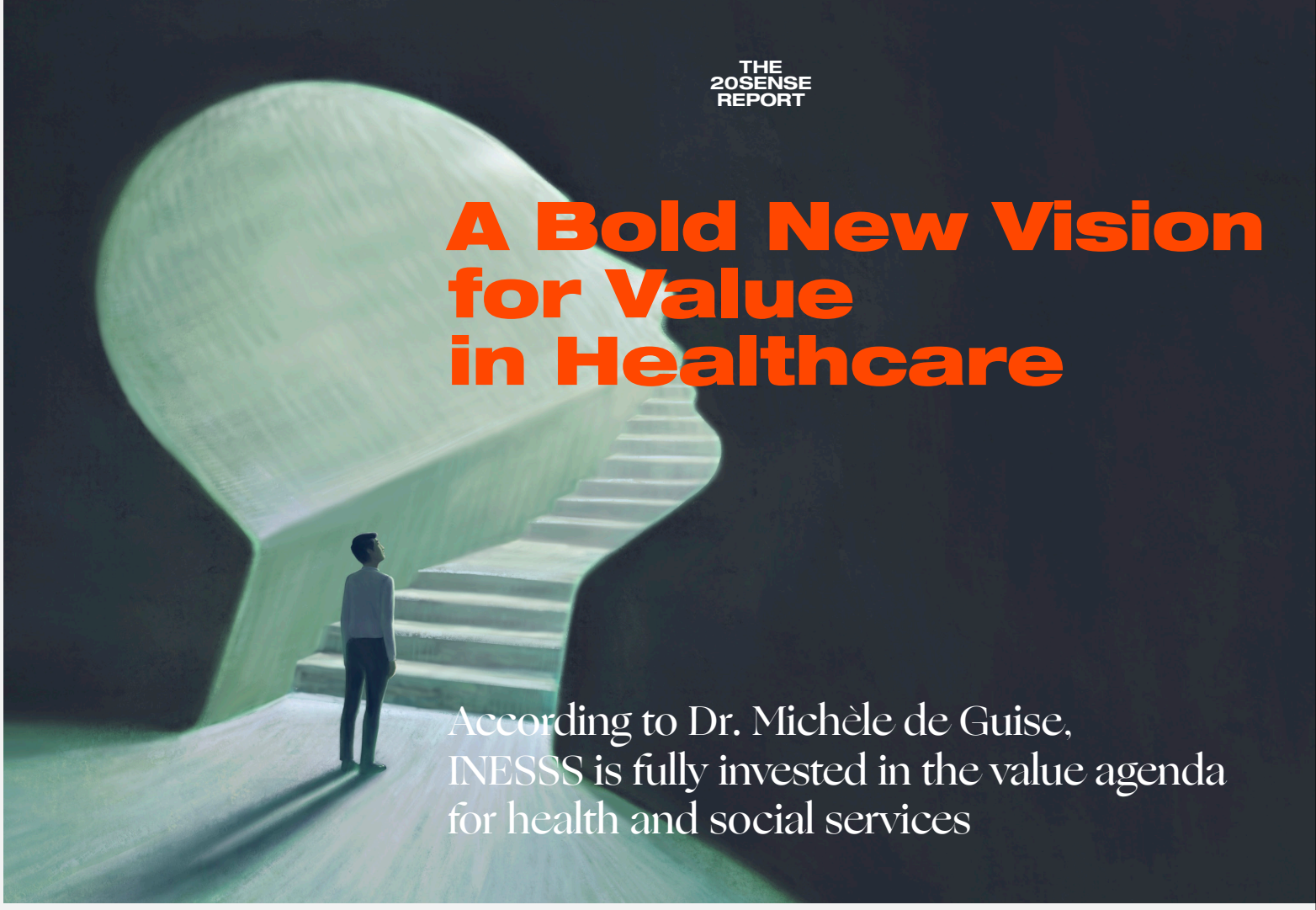

A Bold New Vision for Value in Healthcare

According to Dr. Michèle de Guise, INESSS is fully invested in the value agenda for health and social services

A "whole-person" philosophy permeates Dr. Michèle de Guise's approach to patient care, both in her former life as a practicing cardiologist and in her current position as President and General Manager of INESSS, Quebec's health technology assessment agency. Before landing at INESSS, Dr. de Guise implemented medical innovations in cardiology internationally, including at the Cleveland Clinic. She brought her passion for health promotion and patient experience to the Centre hospitalier de l'Université de Montréal (CHUM), where she served as director of health promotion, director of quality improvement, and later deputy director of professional services. INESSS's holistic mandate, which encompasses health technology assessment, health improvement, and social services, aligns with Dr. de Guise's vision of person-centred total health. As a passionate advocate for VBHC, she was glad to share her thoughts about how to create and assess value.

You have acquired a reputation as a leader and visionary at INESSS. Can you fill us in on your trajectory and current role?

I'm a cardiologist by training, with a particular interest in cardiac failure and heart transplants. At the CHUM, I opened an interdisciplinary cardiovascular rehabilitation clinic to help patients improve and prevent progression of their condition. A subsequent appointment as director of health promotion deepened my interest in health education. Under my direction, we integrated patient partners and patient experts into our care model. After the CHUM, INESSS felt like a natural step. I quickly learned about the challenges of assessing value in complex medications and other interventions where the value isn't always clear from the current evidence. I'm still learning!

Can you provide some background on INESSS's history and current mandate?

In 2003, Quebec had an agency called AETMIS to evaluate health technologies and interventions, and a separate agency, le Conseil du médicament, to evaluate medications. In 2009, AETMIS added assessment of social services to its mandate, and in 2011 AETMIS and the Conseil merged into INESSS. This level of integration makes INESSS quite unique among health technology agencies, but it makes perfect sense: people's experience doesn't divide into separate boxes. Another big milestone occurred in 2016, when we gained access to anonymized patient data from other Health Ministry databases and began assigning a unique INESSS identifier number to each patient. This has given our capacity to evaluate health technologies a giant boost: it means we don't just leverage data from the literature, but can see how new technologies play out in the Quebec

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context. We're now looking to add hospital data to our repertoire. Imagine the rich knowledge that comes from integrating data across the cycle of care, from consultations with clinicians from various specialties, diagnostic exams, and medication use to ER visits, hospitalizations and mortality.

What's more, Quebec's life sciences strategy, which was put in place in 2017 and recently updated, enhances INESSS's role in evaluating innovations at various points in the life cycle. Over the past few years we have worked to strengthen our evaluation methods to ensure they can flex with specific innovations and methodological developments.

How do you define VBHC and what relevance does the concept have to INESSS and the Quebec healthcare system?

I see value as a better quality of care, better safety, and a better experience for the patient. A value-driven healthcare system also looks at health providers' well-being, which of course feeds into the quality of care for patients. Then there's the equity piece: how are people in remote regions going to access a sophisticated new treatment available only in a tertiary hospital in Montreal? In our province this is a constant concern. At INESSS, we aim to integrate all these aspects of value in our strategic plan. You could say we've put value in our DNA.

How do you see real-world data (RWD) intersecting with VBHC, today and in the future?

To make the most of a medication's value, we need to use it optimally within our healthcare system, which means giving it to the right patient at the right time, and RWD can support this aim. It can help us answer such questions as: How do results from clinical trials translate to patients being treated in the real world, who may not have the same health status or comorbidities as clinical trial subjects? Are we giving the medication to the right people? How does it compare to the standard of care in different patient groups? That's how we assess the value of a medication.

Does this mean restricting access to some innovations?

Once the value of a medication has been demonstrated, we should do everything in our power to facilitate access. But when a medication doesn't show value, we need agreed-upon mechanisms to stop recommending and using it. There's no point in giving a medication that doesn't offer value to a patient: it won't work and nobody benefits. Plus, it deprives the patient of a treatment that might work better. That's why we are moving towards a life cycle approach to health technology assessment, which emphasizes value across the entire treatment path and continuously generates and uses real-world data.

What are your thoughts about assessing precision medications?

To my mind, the big challenge lies in evaluating the field of precision medicine as a whole. We're not just talking about medications anymore: cellular therapies, for example, may come in pill form and may have a drug identification number, but they're also complex treatments that have a bearing on the organization of healthcare and health services. We need new ways to conceptualize and assess such treatments. Scientific innovation is happening so fast that we always have to play catch-up. And we're doing it! We're constantly adapting to what comes next, even when we don't always know what "next" looks like.

Can you elaborate on the concept of patient partnership?

Medical treatment has become increasingly complex and we need greater and more varied expertise to inform decisions. Patients have a unique type of expertise because only they can tell us what it's like to live with, say, cancer, what they expect from treatment, and what they get from it. They can also help us understand the impact of side effects in relation to treatment benefits.

How do patients feel about taking on this enhanced role?

They're completely on board. And they show a remarkable understanding of the concept of value. Thanks to our efforts to integrate patients and the public into the drug evaluation process and to make our processes more transparent, patients have come to realize that the state can't take on *all* the risks for uncertain products. The risk ought to be shared. We also aim to communicate transparently with patients about medications with promising but uncertain value. That way, if they gain access to these medications, it's what I call "informed access." There is often a lot of uncertainty around the medium-to-long-term benefits and side effects of novel treatments, and patients need reassurance that there is a monitoring process in place to inform reimbursement decisions.

"How do we spread the risk so we harness the full value of the treatment, while also making adjustments if the value doesn't materialize as hoped?"

How ready is Quebec to incorporate VBHC at all levels of healthcare? Any obstacles you can identify?

I think we're in a good position for VBHC, partly because of INESSS. The term "value" has been democratized, and I sense a political will to incorporate the concept of value into our decision-making processes within the health system. What's missing is full data integration: the different silos aren't talking to each other yet, so it's still difficult to get a full picture of the patient journey. We're also weak on collecting patient-reported outcome measures – one of my preoccupations since my time at CHUM – as well as data on wait times and home care.

How would you like the specialty pharmaceutical space to incorporate value-based practices?

The rigour of industry-led RWD isn't quite where it could be. Ideally, the data should look beyond clinical outcomes and address the impact of a treatment on the healthcare system – things like the need for additional intensive care or staff training. I also see opportunities to ramp up comparative RWE, meaning evaluation of a new treatment against the standard of care. That's what regulators and payers are interested in. Comparing a treatment to placebo doesn't mean as much, because just about all medical conditions already have some form of treatment. Beyond efficacy, we need to ask: Do we have all the relevant information about the added value of a new therapy? Has our research methodology enabled us to capture this crucial information?

How would you like INESSS to use RWE in the future? Any limitations in the use of RWE?

There is a clear need for real-world data to complement randomized controlled trials – but it has to be high-quality data, and registry data may or may not meet that standard. Right now, the quality of RWE varies widely. Going forward, stakeholders need to apply quality standards to the data so they can use it to draw accurate and actionable scientific conclusions.

Sometimes, the nature of the treatment makes it difficult to collect data. Taking the example of a novel medication for a rare condition, it may take years to get enough data to assess the medication's value. Affected people don't have those years to wait, and sometimes you have to make a decision to give them access to the drug right away despite uncertainty about value.

Globally, outcomes-based agreements have been used to ensure timely access to costly medications and to distribute the financial risk of these treatments. How do such agreements integrate into VBHC and do they have a place in the Canadian specialty medicine ecosystem?

These mechanisms aim to distribute the risks associated with treatments that show promise but have as-yet uncertain value, so we don't delay access to patients. There is certainly a role for these treatments, but it's a challenge to determine how best to deploy them. The burden cannot fall solely on the state or the payer, and certainly not on the patient. The question becomes: how to spread the risk so we can harness the full value of the treatment – the right patient at the right time – and at the same time make adjustments if the value doesn't materialize as hoped?

In their current form, reimbursement agreements often incur a heavy clinical and administrative burden, with limited clinical evidence for the therapy in question. This makes it essential for stakeholders to work together to develop realistic and efficient frameworks for managing and mitigating the risks of certain innovations, while ensuring the agreements include clear direction on how to use the data collected to support them. The current shift toward a life-cycle approach to drug evaluation is a step in this direction.

What value-based directions and initiatives can we expect from INESSS in the months and years to come? What possibilities get you most excited?

I hope to strengthen our ability to respond to patient, clinician, and decision-maker concerns in a timely manner. The pandemic fast-tracked our agility and we don't want to lose that momentum. I'm especially excited about working toward a learning healthcare system – a system that constantly evaluates itself and adapts to new innovations and needs.