AGHPS 13th Leadership Summit 2023

Ontario Health's Neurostimulation Procedures Provincial Program

OCTOBER 27, 2023

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Neurostimulation Procedures Advisory Committee Chair, MHA CoE

Co-Chief, General Adult Psychiatry and Health Systems Division, CAMH

Temerty Chair In Therapeutic Brain Intervention

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MHA CoE

- The MHA CoE supports Ontario in building **a comprehensive and connected mental health and addictions system**

- It plays a critical role in overseeing the delivery and quality of mental health and addictions services and supports, including system management, supporting quality improvement, disseminating evidence, and setting service expectations

- The MHA CoE will also help implement **key priorities within the Roadmap to Wellness**, the province's plan to build a comprehensive and connected mental health and addictions system

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Bringing together the Government's strategy and COVID recovery planning to shape our clinical priorities and core functions

Roadmap to Wellness
Four pillars

1. Improving quality

2. Expanding existing services

3. Implementing innovative solutions

4. Improving access

Clinical Areas of Focus

1. Depression and anxiety-related disorders

2. Schizophrenia and psychosis

3. Eating disorders

4. Substance use disorder

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Program & Performance Management	Evidence-Based Services	Monitoring & System Performance	Access & System Navigation	Stakeholder Engagement	Data & Digital Strategy

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Indigenous Health Equity is being embedded in all CoE clinical priorities and core functions

Depression and Anxiety Related Disorders Provincial Program

Provincial Program Working Definition

Provincial Program oversees and coordinates the management and continuous quality improvement for an identifiable disease/condition that is common and/or burdensome for defined populations

The Depression and Anxiety-related Disorders (DARD) Provincial Program aims to:

- Provide oversight and coordination for DARD to maximize population level benefits and minimize harms

- Bridge gaps between evidence and data, policy and clinical practice

- Provide supportive infrastructure, coordination and integration through funding, accountability, leadership, communications and stakeholder relations

- Have information technology and mechanisms to enable routine monitoring, evaluation and reporting on program and system-level impacts for continuous quality improvement
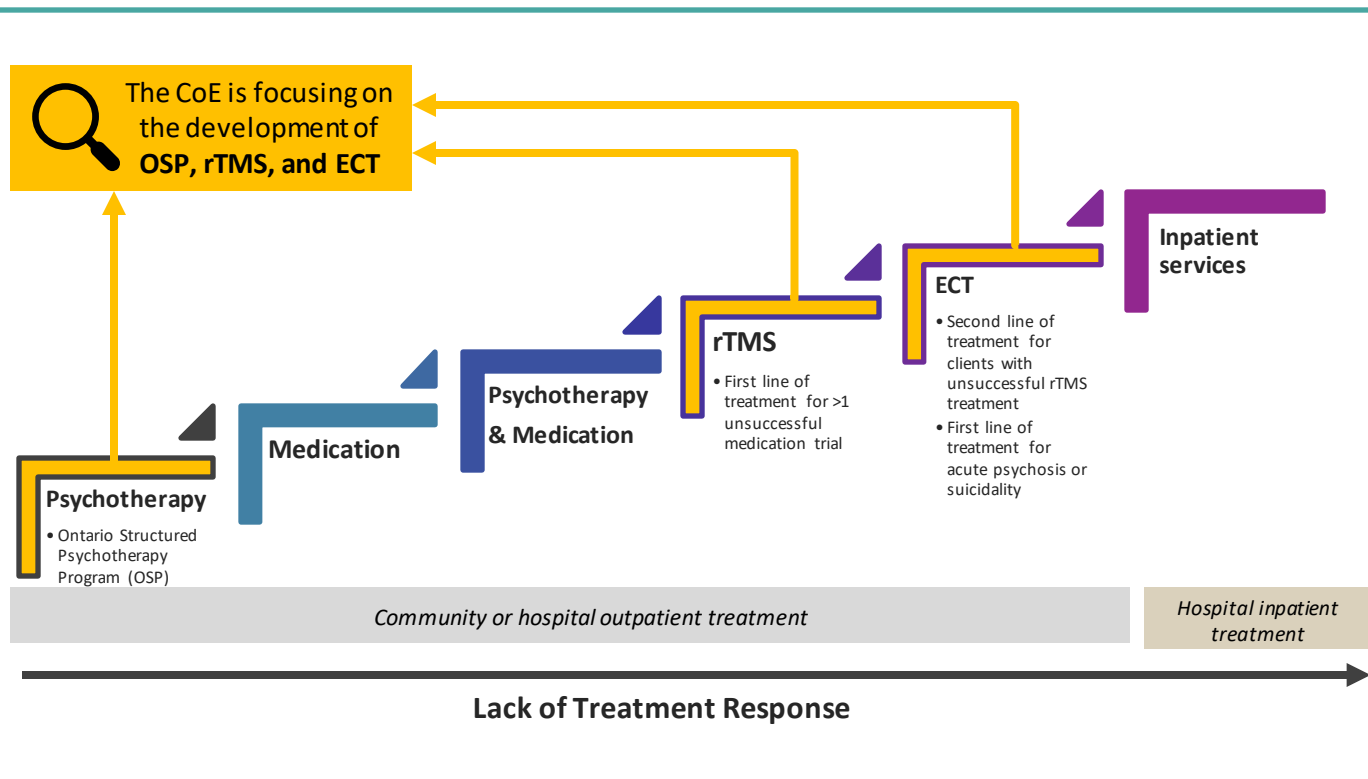
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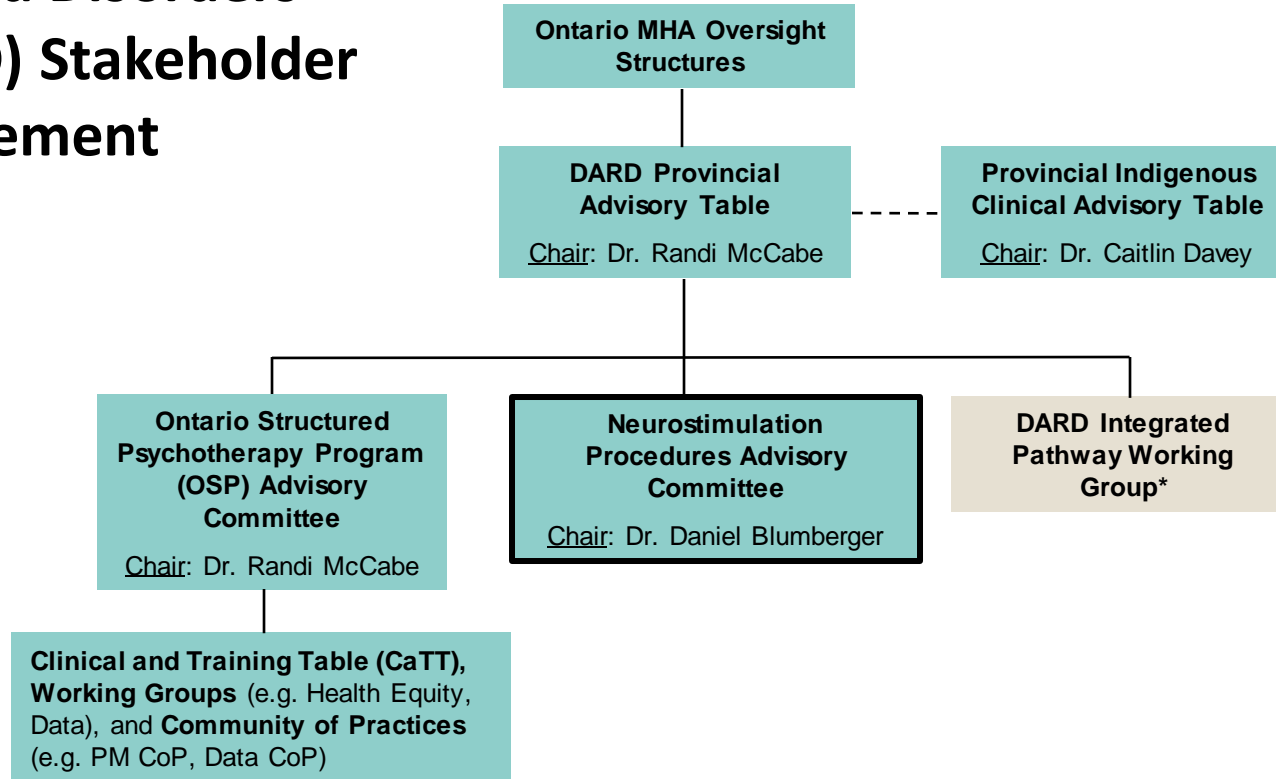# Treatment for Depression and Anxiety-Related Disorders

TREATMENT

Individuals receive treatment through community and hospital outpatient care, or hospital inpatient care. Level of care ranges from low intensity, high intensity.

The CoE is focusing on the development of **OSP, rTMS, and ECT**

Psychotherapy
- Ontario Structured Psychotherapy Program (OSP)

Medication

Psychotherapy & Medication

rTMS
- First line of treatment for >1 unsuccessful medication trial

ECT
- Second line of treatment for clients with unsuccessful rTMS treatment
- First line of treatment for acute psychosis or suicidality

Inpatient services

Community or hospital outpatient treatment

Hospital inpatient treatment

Lack of Treatment Response

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5

Depression and Anxiety Related Disorders (DARD) Stakeholder Engagement

Ontario MHA Oversight Structures

DARD Provincial Advisory Table

Chair: Dr. Randi McCabe

Provincial Indigenous Clinical Advisory Table

Chair: Dr. Caitlin Davey

Ontario Structured Psychotherapy Program (OSP) Advisory Committee

Chair: Dr. Randi McCabe

Neurostimulation Procedures Advisory Committee

Chair: Dr. Daniel Blumberger

DARD Integrated Pathway Working Group*

Clinical and Training Table (CaTT), **Working Groups** (e.g. Health Equity, Data), and **Community of Practices** (e.g. PM CoP, Data CoP)

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*Stakeholder group not yet established   6

Neurostimulation Procedures Provincial Program

Neurostimulation Procedures Provincial Program: Key Inputs

Key Inputs: Mandates and directives for the MHA CoE

1. Government of Ontario's Roadmap to Wellness
2. Ontario Health (OH) Mandate Letter
3. OH's 2022/23 Annual Business Plan

Key Inputs: Foundational work specific to Neurostimulation Procedures:

1. COVID-19 Recovery Guidance Document

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Neurostimulation Procedure Recovery Plan Recommendations

Access, Capacity and Sustainability

- Implementation of new service model to create sites with adequate and consistent demand, flow, structures and processes that will result in an efficient system of high-quality services. This model will maximize scarce HHR through levels of service provider sites

- Ensure services are supported by infrastructure (procedure room time, PACU) and human resources to provide high-quality care

- Implement a model which enables delivery of electroconvulsive therapy (ECT) and repetitive transcranial magnetic stimulation (rTMS) over multiple sites

- Develop education and outreach strategy for potential referring clinicians regarding neurostimulation procedures
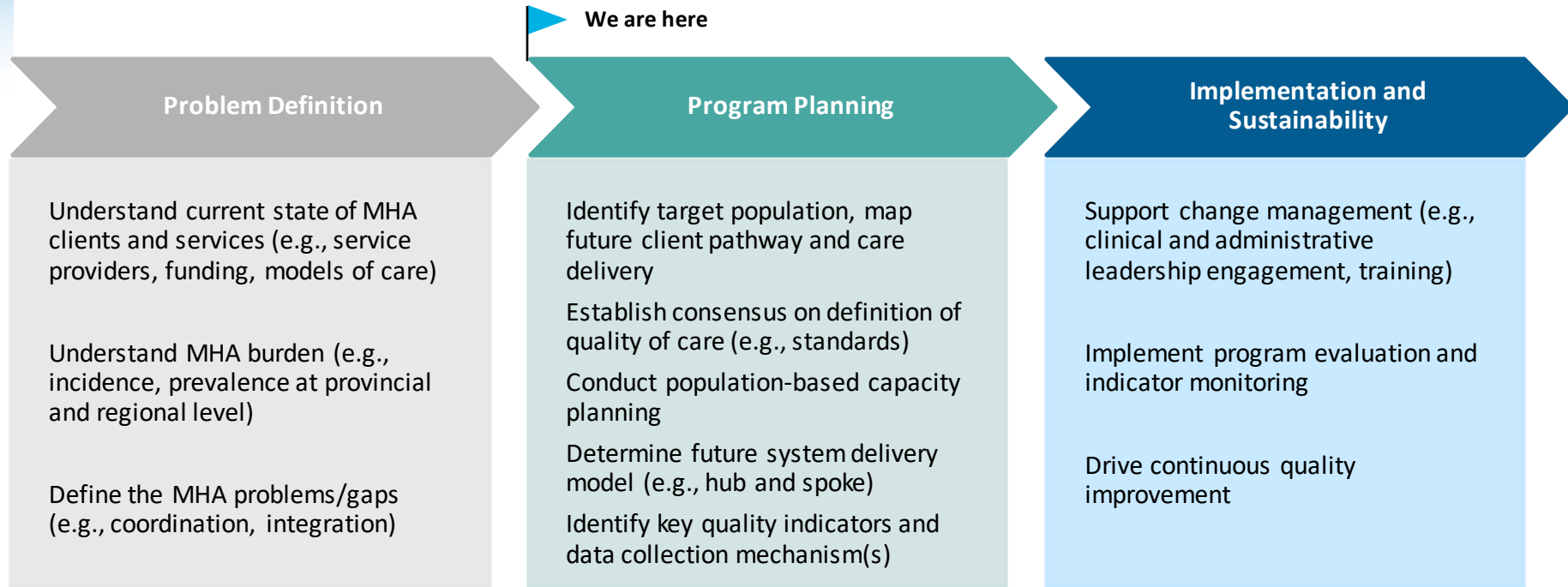
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Neurostimulation Procedure Recovery Plan Recommendations

Quality and Safety

- Develop a mentorship strategy for sharing expertise between providers

- The strategy should address communication regarding individual patient needs and mechanisms of sharing best practices

- Develop evidence-based clinical and quality guidance documents for
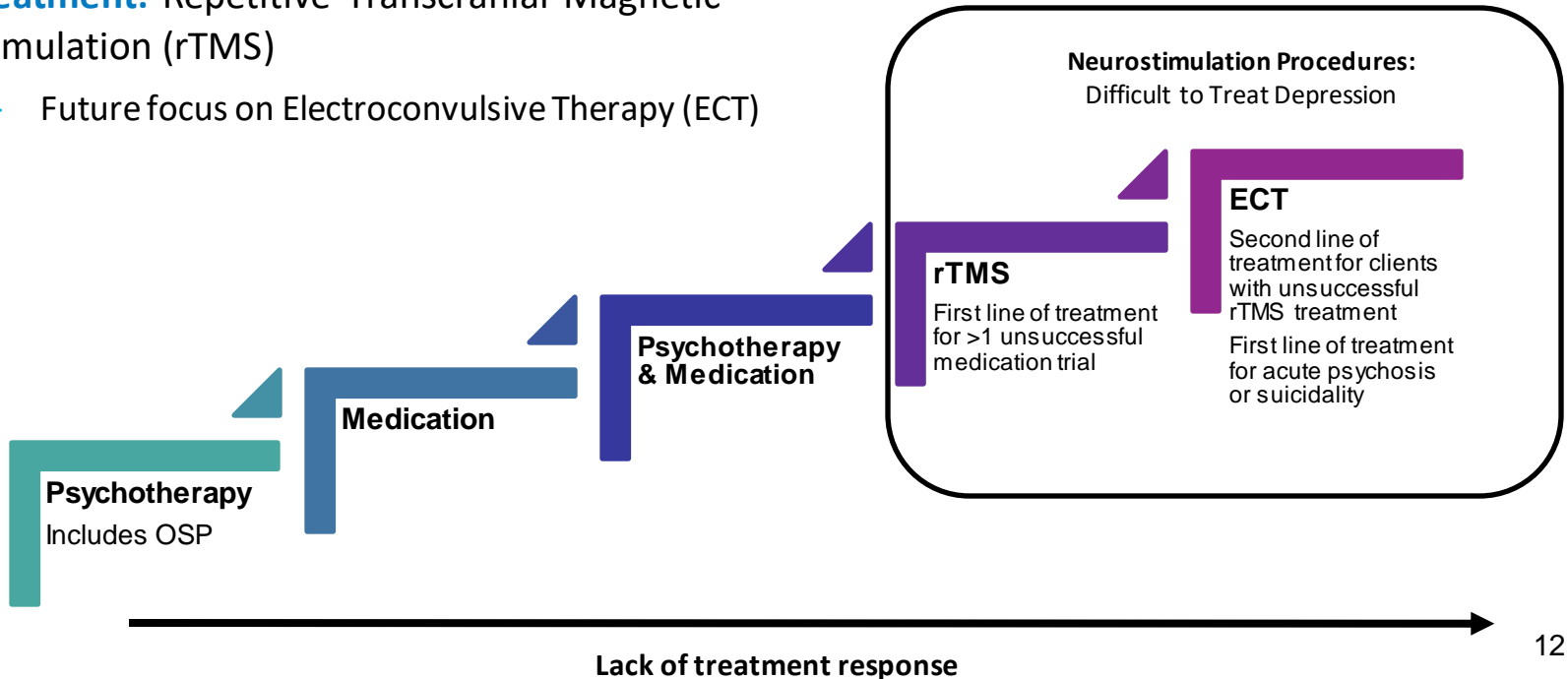
  - ECT

  - rTMS

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Approach to Create a Provincial Program

We are here

Problem Definition	Program Planning	Implementation and Sustainability
Understand current state of MHA clients and services (e.g., service providers, funding, models of care) Understand MHA burden (e.g., incidence, prevalence at provincial and regional level) Define the MHA problems/gaps (e.g., coordination, integration)	Identify target population, map future client pathway and care delivery Establish consensus on definition of quality of care (e.g., standards) Conduct population-based capacity planning Determine future system delivery model (e.g., hub and spoke) Identify key quality indicators and data collection mechanism(s)	Support change management (e.g., clinical and administrative leadership engagement, training) Implement program evaluation and indicator monitoring Drive continuous quality improvement

Enablers: Stakeholder Engagement and Partnership (e.g., OH Regions, Clinical Stakeholders), Quality Improvement Processes, Funding, Evidence and Data, Program and Performance Management, MHA oversight model

Neurostimulation Procedures Provincial Program

- **Population:** Adults with difficult to treat depression

- **Setting:** Publicly funded hospitals

- **Treatment:** Repetitive Transcranial Magnetic Stimulation (rTMS)
    - Future focus on Electroconvulsive Therapy (ECT)

Neurostimulation Procedures:
Difficult to Treat Depression

ECT
Second line of treatment for clients with unsuccessful rTMS treatment
First line of treatment for acute psychosis or suicidality

rTMS
First line of treatment for >1 unsuccessful medication trial

Psychotherapy & Medication

Medication

Psychotherapy
Includes OSP

Lack of treatment response

Prioritizing rTMS for Provincial Planning

- Focusing on one treatment allows us to meaningfully support the change management activities required for successful implementation

- An rTMS provincial program has the potential to:

  - Leverage existing capital investments to develop a value-based system

  - Increase access to evidence-based rTMS treatment with minimal out-of-pocket costs for treatment

  - Treat thousands of people with difficult to treat depression on an annual basis, resulting in greater functional outcomes and preventing further treatment resistance

  - Reduce pressures on ECT

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Monitoring ECT Recovery

- Sites delivering ECT scaled back offerings during the COVID-19 pandemic, resulting in lower treatment volumes

- To date, ECT volumes have not returned to pre-pandemic levels

Impact of COVID-19 on ECT Volumes
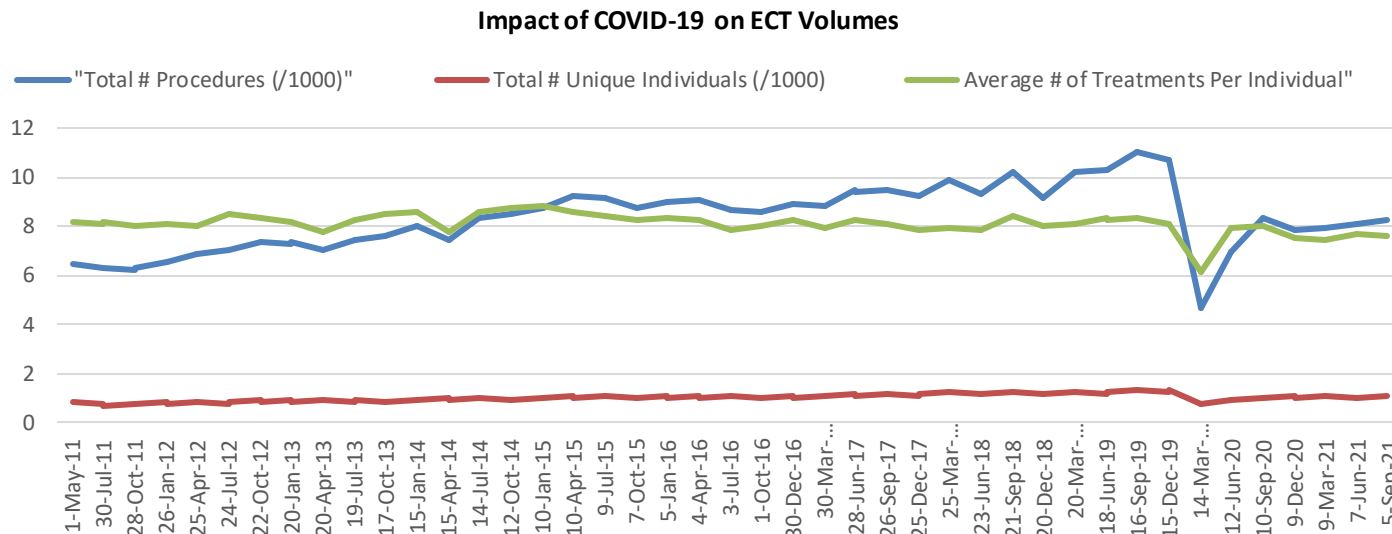
Figure 1. Crude rate of all ECT treatments per 1000 individuals aged 18 and older in Ontario, from May 1, 2011, to December 3, 2021. (Data source: OHIP, RPDB; Date prepared: August 18, 2022; Prepared by: ICES).

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Monitoring ECT Recovery

- While developing the rTMS provincial program, we will continue to monitor ECT recovery in FY23/24

  - The Institute for Clinical Evaluative Sciences (ICES) will be quantifying the volume of ECT procedures and determine where ECT is delivered

  - These results will be used to understand the demand for difficult to treat depression treatment in Ontario

- Provincial planning for ECT is anticipated to begin in FY25/26*

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Neurostimulation Procedures Provincial Program Strategic Framework (2023-2026)

Goal: Enhance the accessibility, standardization, and quality of neurostimulation procedures in Ontario

| Improve access to, and quality of, evidence-based neurostimulation procedures care | Establish regional service delivery models to enable access to timely care close to home | Increase neurostimulation procedures expertise across the province | Leverage data to enable provincial planning, monitor performance, and measure outcomes |

Equity will be embedded in all aspects of the provincial program

System enablers: Data and measurement, evidence, stakeholder engagement

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MHA CoE's Programmatic Approach

Applying the approach that has been successful for cancer, renal, cardiac and stroke provincial programs to mental health and addictions

Who's responsible for change?

Program & Performance Management

Establish a central point of accountability, funding and oversight for mental health and addictions services

What changes in care do we want?

Evidence-based Services

Standardize and monitor the quality and delivery of core evidence-based services and clinical care across the province to provide quality care and more consistent patient experience

How will we know change is happening?

Monitoring & System Performance

Create common performance indicators and shared infrastructure to disseminate evidence and set service expectations

Who informs change?

Stakeholder Engagement

Collaborate with clinicians and other experts, and engaging with the public, clients and caregivers

What data are needed to drive change?

Data & Digital Strategy

Implement an Information Management and Information Technology (IM/IT) platform for the primary purposes of collecting data for funding, measurement and planning

How does change help people in need?

Access & System Navigation

Provide resources and support through provincial and regional leadership to Ontario Health Teams as they connect patients to the different types of mental health and addictions care they need and help them navigate the complex system

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17
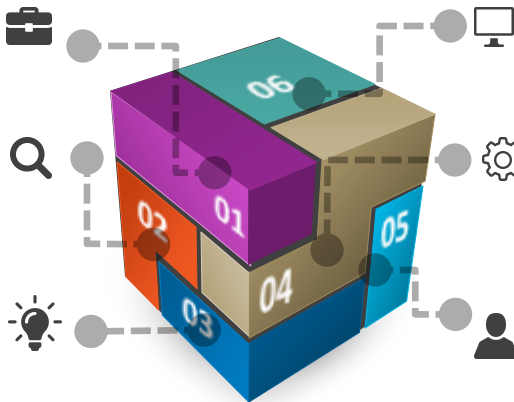
1. Evidence-Based Clinical Model of Care

A standardized evidence-base clinical model of care will include:

✓ **Leverage the OHTAC Report to develop evidence-based standards,** which outline the minimum quality expectations for all rTMS programs in Ontario. These standards will ensure that all Ontarians meeting the eligibility criteria will receive comprehensive, high quality, evidence-informed care, treatment and support

✓ Defined **eligibility criteria**

• This work will be designed by the Neurostimulation Procedures Advisory Committee and the Depression and Anxiety Related Disorders Provincial Advisory Table and will involve robust stakeholder engagement

  • Membership will include people with lived experience, service providers, and clinical experts

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Clinical outcomes in a large registry of patients with major depressive disorder treated with Transcranial Magnetic Stimulation

- **Methods:** data collected from 103 sites, 7759 patient with MDD (5010 in ITT analysis)

- **Results:**

Table 2
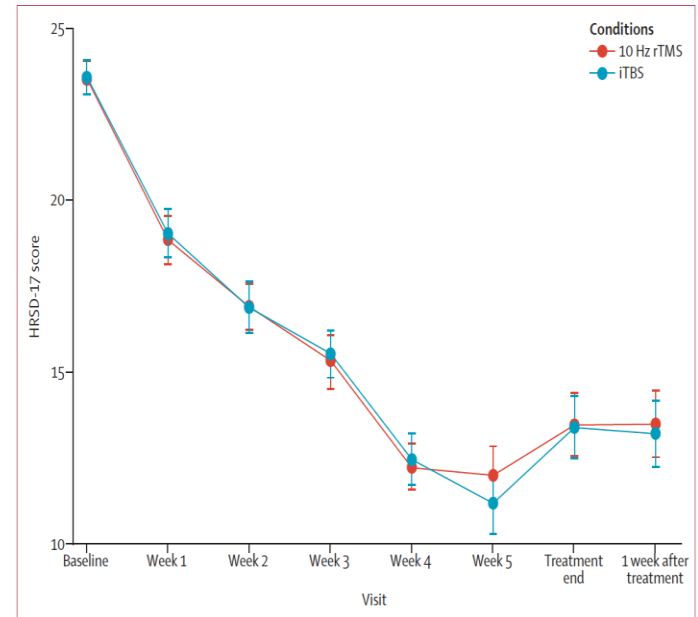PHQ-9 treatment outcomes in the intent-to-treat and completer samples.

| | PHQ-9 outcomes | | | |
| | Intent-to-treat sample | | Completer sample | |
	Total ($N = 5010$)	Left only ($N = 2764$)	Total ($N = 3814$)	Left only ($N = 2053$)
Baseline PHQ-9	19.8 ± 4.1	19.4 ± 4.2	19.8 ± 4.1	19.3 ± 4.1
LOCF PHQ-9	9.6 ± 6.8	9.0 ± 6.7	8.6 ± 6.4	7.9 ± 6.2
Difference (Pre-Post)	10.2 ± 6.8	10.4 ± 6.8	11.1 ± 6.6	11.4 ± 6.6
Response rate	57.7%	60.6%	65.0%	68.9%
Remission rate	27.9%	31.2%	31.7%	35.8%

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Effectiveness of theta burst versus high-frequency repetitive transcranial magnetic stimulation in patients with depression (THREE-D): a randomised non-inferiority trial
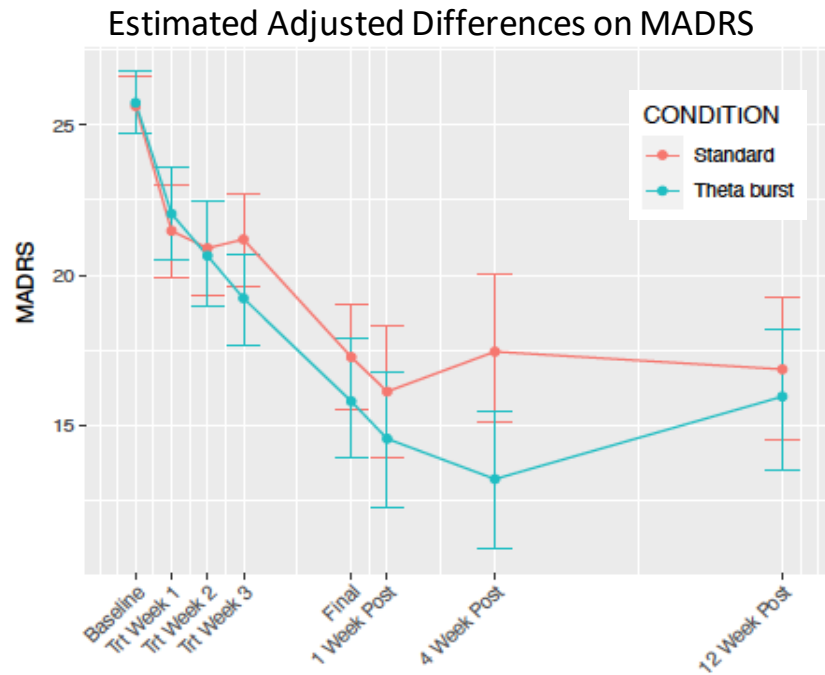
- **Methods**: 192 participants with TRD received 10 Hz and 193 received iTBS, administered for 4-6 weeks at 120% RMT

- **Acute Phase:** 20 daily sessions
  - If achieve < 30% reduction on HRSD-17 after 20 sessions, will receive 10 more sessions to optimize response

- **Follow Up:** 1, 4, and 12 weeks after treatment

	Number of participants assessed (10 Hz rTMS group/ iTBS group)	10 Hz rTMS group	iTBS group	p value
HRSD-17				
Baseline	385 (192/193)	23·5 (4·4)	23·4 (4·3)	..
After treatment	385 (192/193)	13·4 (7·8)	13·4 (7·9)	0·0011
Response	385 (192/193)	91 (47%)†	95 (49%)†	0·0005
Remission	385 (192/193)	51 (27%)†	61 (32%)†	0·0005

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Blumberger et al. 2018 Lancet   20

Effectiveness of Standard Sequential Bilateral Repetitive Transcranial Magnetic Stimulation vs Bilateral Theta Burst Stimulation in Older Adults With Depression

- **Methods:** standard LFR (1Hz, 10 min) followed by HFL (10Hz, 37.5 min)

- Right cTBS (40 sec) followed by left iTBS (3min 9 sec)

- N = 172, 60 yrs and older with TRD

- **Results:** meaningful remission rates of 35% for TBS and 33% for rTMS

- No difference adverse effects or drop out rates despite higher pain scores with TBS

Estimated Adjusted Differences on MADRS

Blumberger et al., JAMA Psychiatry 2022 21

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2. System Planning and Delivery Model

- The system planning and delivery model will embed client-first principles such as integration, coordination and accessibility.

- The system planning and delivery model will:

    ✓ Utilize **capacity planning** to understand the regional supply and demand for rTMS services and ensure data-driven decisions to ensure necessary infrastructure for rTMS treatment is in place across the province

    ✓ Leverage a **hub and spoke model**, in which the hubs will be responsible for overseeing the quality of services offered at spoke sites

    ✓ Ensure the **funding model** for rTMS is tied more directly to high-quality care that is defined by the provincial clinical model of care

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Patient-level Characteristics and Inequitable Access to Inpatient Electroconvulsive Therapy for Depression: A Population-based Cross-sectional Study

- **Methods**: identified psychiatric inpatients with MDE admitted to hospital $\geq$3 days in Ontario, (2009-2017)

- **Results**: nearly 1 in 10 patients hospitalized for depression received ECT (75,429 admissions, 9.2% ECT)

- Likelihood of ECT was greater for:

Sociodemographic:

- Older adults

- Were married/partnered

- Had postsecondary education

- Lived in rural vs urban dwelling

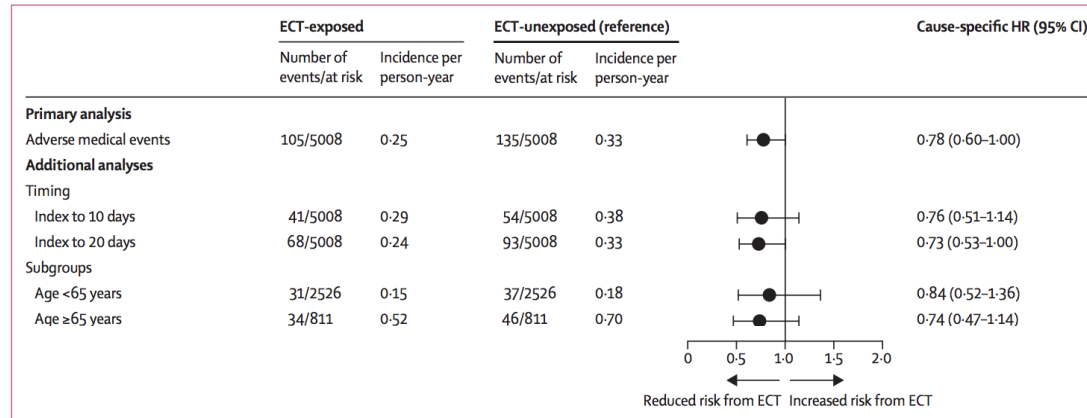- Resided in highest neighborhood income quintile

Clinical:

- Unipolar depression vs bipolar

- With psychotic features vs without

- More severe depressive symptoms

- Incapable to consent

- ***Reduced** with comorbid substance use disorders and several medical comorbidities

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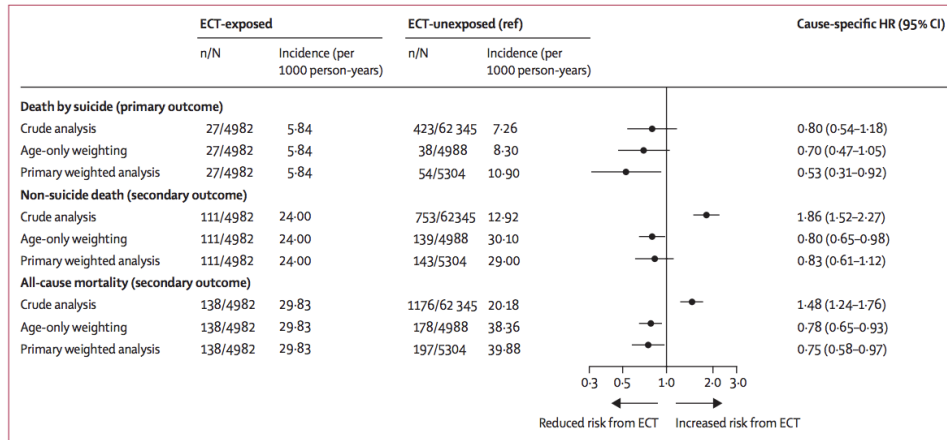Mental Health and Addictions
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Risk of serious medical events in patients with depression treated with electroconvulsive therapy: a propensity score-matched, retrospective cohort study

- **Methods:** Propensity score-matched, retrospective cohort study

- **Outcome**: serious medical events- hospitalization for medical reasons or non-suicide death within 30 days from ECT or matched unexposed

- **Results:** no evidence of increased risk for SME with ECT, and risk of suicide was significantly reduced

	ECT-exposed		ECT-unexposed (reference)			Cause-specific HR (95% CI)
	Number of events/at risk	Incidence per person-year	Number of events/at risk	Incidence per person-year		
Primary analysis						
Adverse medical events	105/5008	0·25	135/5008	0·33		0·78 (0·60–1·00)
Additional analyses						
Timing						
Index to 10 days	41/5008	0·29	54/5008	0·38		0·76 (0·51–1·14)
Index to 20 days	68/5008	0·24	93/5008	0·33		0·73 (0·53–1·00)
Subgroups						
Age <65 years	31/2526	0·15	37/2526	0·18		0·84 (0·52–1·36)
Age ≥65 years	34/811	0·52	46/811	0·70		0·74 (0·47–1·14)

Reduced risk from ECT   Increased risk from ECT

Risk of suicide death following electroconvulsive therapy treatment for depression: a propensity score–weighted, retrospective cohort study in Canada

- **Methods:** Propensity score-matched, retrospective cohort study

- **Outcome**: death by suicide identified using administrative health records within 1 year following discharge

- **Results:** <67 000 hospitalization records (ECT, age 57 + 17; unexposed, age 44 + 17)

  - ECT associated with reduced risk of suicide death 50% less!

	ECT-exposed		ECT-unexposed (ref)			Cause-specific HR (95% CI)
	n/N	Incidence (per 1000 person-years)	n/N	Incidence (per 1000 person-years)		
Death by suicide (primary outcome)						
Crude analysis	27/4982	5·84	423/62 345	7·26		0·80 (0·54–1·18)
Age-only weighting	27/4982	5·84	38/4988	8·30		0·70 (0·47–1·05)
Primary weighted analysis	27/4982	5·84	54/5304	10·90		0·53 (0·31–0·92)
Non-suicide death (secondary outcome)						
Crude analysis	111/4982	24·00	753/62345	12·92		1·86 (1·52–2·27)
Age-only weighting	111/4982	24·00	139/4988	30·10		0·80 (0·65–0·98)
Primary weighted analysis	111/4982	24·00	143/5304	29·00		0·83 (0·61–1·12)
All-cause mortality (secondary outcome)						
Crude analysis	138/4982	29·83	1176/62 345	20·18		1·48 (1·24–1·76)
Age-only weighting	138/4982	29·83	178/4988	38·36		0·78 (0·65–0·93)
Primary weighted analysis	138/4982	29·83	197/5304	39·88		0·75 (0·58–0·97)

0·3 0·5 1·0 2·0 3·0

← Reduced risk from ECT   Increased risk from ECT →

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Cost–Utility Analysis of Electroconvulsive Therapy and Repetitive Transcranial Magnetic Stimulation for Treatment-Resistant Depression in Ontario

- **Methods:** Cost–utility analysis of lifetime costs and benefits to society of rTMS and ECT as first-line treatments for TRD

- Used Markov model- simulates costs and health benefits of patients over lifetime in 10,000 individuals

- Data extraction:

  - Treatment efficacy and health utility data- from randomized controlled trials and meta-analyses

  - Direct costing data- from national/provincial costing databases

  - Indirect costs (absenteeism, transportation, lost wages, long-term disability payments, medication costs)- from government records

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Cost–Utility Analysis of Electroconvulsive Therapy and Repetitive Transcranial Magnetic Stimulation for Treatment-Resistant Depression in Ontario

- **Results:** rTMS dominated ECT- less costly and led to better health outcomes

  - rTMS patients gained 0.96 additional QALYs over lifetime while costing $46,094 less than ECT

Scenario Analysis.

Scenario	Difference in Average Lifetime Costs[a]	Difference in Average Lifetime QALYs[b]	ICER
Base case	−$46,094	0.96	rTMS dominates
No rTMS nonresponders switch to ECT	−$38,966	0.77	rTMS dominates
Eighty percent of rTMS nonresponders switch to ECT	−$46,614	1.19	rTMS dominates
Direct costs only	−$6,649	0.98	rTMS dominates
All ECT treatments outpatient	−$31,560	0.95	rTMS dominates
Equal maintenance therapy efficacy (51%)	−$43,380	0.91	rTMS dominates
ECT response rate twice rTMS response rate (35%, 70%)	−$37,511	0.64	rTMS dominates
Max lifetime acute treatments: ECT (4) rTMS (4)	−$15,814	−0.23	$69,886[c]
Max lifetime acute treatments: ECT (4) rTMS (5)	−$19,166	−0.06	$327,313[c]
Global discount @ 5%	−$37,611	0.76	rTMS dominates
Global discount @ 3.5%	−$41,452	0.83	rTMS dominates
1-Year horizon	−$15,758	0.03	rTMS dominates
2-Year horizon	−$16,957	0.00	$11,192,665[c]

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Repetitive Transcranial Magnetic Stimulation for People With Treatment-Resistant Depression: Recommendation

- Based on guidance from OHTAC, recommends publicly funding rTMS for TRD

  - **Overall clinical benefit**- <u>most</u> rTMS modalities lead to lower depression scores and higher response rates vs sham

  - **Patient preferences and values**- value autonomy in choosing treatment; see rTMS as potentially effective and less complex treatment vs. ECT, with minimal side effects

  - **Equity of access and patient care**- limited distribution in Ontario that does not promote equity of access; outpatient clinics can provide rTMS; unlike ECT, does not require accompaniment to treatment

  - **Cost-effectiveness**- HF rTMS or iTBS (followed by stepped care ECT) less costly and more effective than ECT alone; less costly than pharmacotherapy alone

  - **Feasibility of adoption into health system**- publicly funding rTMS result in additional costs of $63.2 million over next 5 years

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Performance Management & Accountability

- **Key provincial indicators** to measure and monitor client outcomes and experiences to ensure the Neurostimulation Procedures program continues to meet the needs of Ontarians

- Clear **accountability** and expectation for rTMS service providers to adhere to clinical quality standards and commit to monitoring and responding to performance results for key provincial indicators

- The cornerstone of this work is the **MHA CoE's Data and Digital Initiative**
  - The MHA Provincial Dataset will collect client-level, standardized data elements that support direct service delivery and enable consistent and comparable reporting of service utilization, client outcomes & client characteristics.

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Upcoming Neurostimulation Procedures Webinar

- The CoE will be hosting a Neurostimulation Procedures Webinar on **Thursday, November 9th from 3-4pm**

To register for the event:

https://zoom.us/webinar/register/WN_ARemgFTbTyCxqYuqSU_fUg

Appendix

Key Input: Roadmap to Wellness

Pillar 1 – improving quality: enhancing services across Ontario
- Core services framework
- Data and digital

Pillar 2 – expanding existing services: investing in priority areas
- Child and youth mental health
- Mental health and justice services (safe beds, addictions withdrawal management services, mobile crisis teams)
- Supports for police and correctional staff and Ontario's first responders
- Supportive housing
- Indigenous people and communities
- Francophone community

Pillar 3 – implementing innovative solutions: filling gaps in care
- Ontario Structured Psychotherapy (OSP) Program
- Children and youth with autism spectrum disorder and mental health issues
- Expanding addictions services - treatment and withdrawal management (RAAM clinics) and consumption and treatment services (CTS)
- Youth Wellness Hubs

Pillar 4 – improving access: a new provincial program and approach to navigation
- Coordinated access to MHA core services
- Ontario Health Teams (OHTs)

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Roadmap to wellness: a plan to build Ontario's mental health and addictions system | ontario.ca

Key Input: OH Mandate Letter

- From the Office of the Minister of Health to the Chair of the Ontario Health Board

- Letter sets out expectations and direction for Ontario Health in 2022/23 pursuant to the requirements of the Agencies and Appointments Directive

- Identifies 11 priorities for Ontario Health to focus on in 2022/23, including one for mental health and addictions
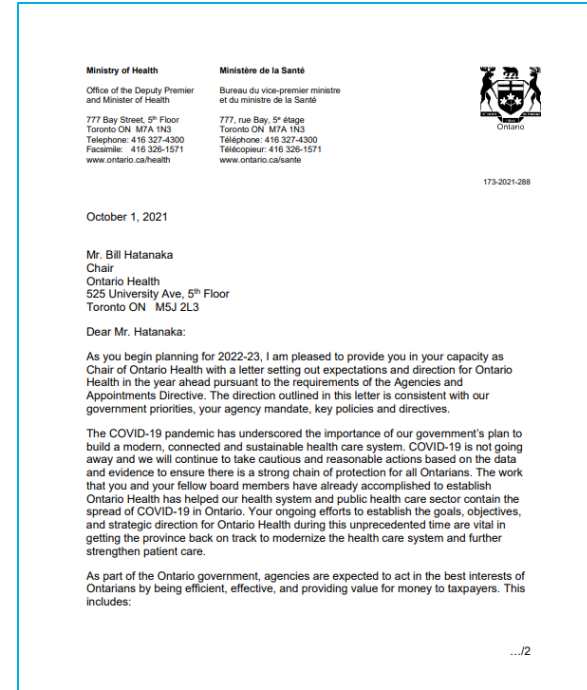
Key Input: OH Mandate Letter

- Priority #2 – Lead health system recovery from the COVID-19 pandemic with a focus on reducing inequities for priority populations, under the following recovery objectives/areas:

  - Increase overall access to community MHA services, including key areas: **anxiety and depression**, opioid and alcohol use disorders, and eating disorders, in alignment with the Roadmap to Wellness

- Priority #6 – Support the MHA CoE to deliver on its requirement to implement the Roadmap to Wellness, with a particular focus on:

  - OSP Program

  - Mobile Mental Health Clinics

  - MHA Data-Digital Initiative

  - Provincial core services and needs-based planning

  - MHA Provincial Coordinated Access

  - Supportive housing (supporting the MOH)

  - Timely access to MHA services

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Key Input: OH 2022/23 Annual Business Plan

Transform Care with the Person at the Centre

2.1 Support improved access to high quality Mental Health and Addictions care

2.2 Improve a person-centred continuum of long-term care (and support the fixing long-term care plan)

2.3 Expand access to high-quality, integrated care through accelerated implementation of Ontario Health Teams (OHTs)

2.4 Support people in the community (Integrate home care to points of care)

2.5 Digitally enable patient navigation and seamless patient transitions (implement Digital First for Health Strategy)

2.1 Support improved access to high quality Mental Health and Addictions care

YEAR ONE: 2022/23

Improve access to and quality of care for depression and anxiety-related disorders by:

- Increase access to high-quality and measurement-based care, through expanding the capacity of the Ontario Structured Psychotherapy (OSP) program and integrating internet-based cognitive behavioural therapy.
- Identify where additional services may be needed to support a continuum of care for depression and anxiety-related disorders.
- Begin phased approach with three OHTs to develop and implement care pathways related to screening for depression.

Improve access to and quality of care for people experiencing substance use, eating disorders and psychosis by:

- Develop a provincial oversight and stakeholder engagement strategy to support operationalizing priority recovery recommendations.
- Develop a measurement strategy, supported through the expansion of the provincial minimum data set, in alignment with anxiety and depression.

Improve system strategy and operations by:

- Improve access to mental health and addictions services in rural and underserved populations by supporting initiatives such as mobile clinics and French Language virtual counseling services.
- Begin development of a plan for Indigenous mental health and addictions care.
- Enhance access, quality and informed planning of mental health and addictions services via digital and virtual tools.
- Begin scaling up the collection of mental health and addictions data from community providers to support planning, funding, and monitoring quality.
- Begin development and implementation of a performance measurement framework for priority clinical areas and related populations.
- Develop an implementation approach for mental health and addictions coordinated access that aligns with system-level improvements. This approach will be supported by the development of a system level performance measurement framework, starting with the identification of key indicators.

YEAR TWO: 2023/24

Improve Clinical Programs

- Implement the Ontario Structured Psychotherapy performance management cycle and begin to align funding and quality expectations.
- Initiate improvements in quality, equity and performance of targeted clinical areas of focus.

Improve System Strategy and Operations

- Continue mental health and addictions services planning and improvements with OHTs and other integrated care programs for priority clinical areas.
- Begin implementation of a plan for Indigenous mental health and addictions care.
- Continue to enhance and improve access to, integration of, and quality of care via digital and virtual tools.
- Expand and digital initiatives in the community mental health and addictions sector.