

# Presumed Consent “Opt Out”

HUMAN ORGAN AND TISSUE DONATION ACT (HOTDA)

JOURNEY TO A BETTER PLACE

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We need more donors



# Surprise!

Nova Scotia

## Organ donor rule change may presume consent in Nova Scotia



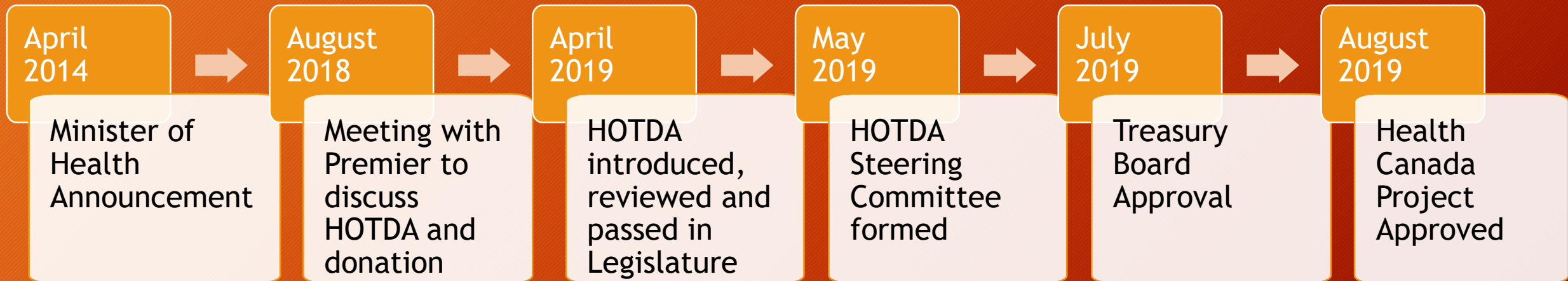
Health Minister Leo Glavine says Nova Scotia may be ready for a reverse onus legislation

CBC News · Posted **Apr 24, 2014** 4:06 PM AT | Last Updated: April 25, 2014

# Presumed Consent

- Higher donation rates in many (but not all) countries with presumed consent ( opt out )
- Increased donation (30%?) when this is brought in
- The ***system change***...which includes presumed consent as a component, is the principal driver
- Difficult to tease out the effect of presumed consent *in isolation*
- Can it really be just because more potential donors are now consented (...was their consent rate that low before this change)

# Human Organ and Tissue Donation Act (HOTDA) Timeline



# The early days..

April 2014

Minister of Health  
Announces that  
NS is considering  
Presumed Consent  
Legislation



2017-2018

Donation  
performance falls,  
some provinces  
thrive  
Developing a plan  
to re-boot the  
donation program



August 2018

Premier requests a meeting to discuss  
Presumed Consent (Opt out)

Senior Leadership invited (NSHA CEO,  
Minister of Health, Justice, CCOD,  
MOTP, RTB, Sr Director of Critical  
Care, Chair Critical Care, Lead of  
provincial critical care program)

Frank, lengthy discussion regarding  
potential challenges and  
opportunities

# The message to the Premier

- NS had been the national leader in donation, not anymore
  - Provinces that invested improved, we were stagnant
- Presumed consent (opt out) may increase donation
- A law is just words on paper
- NS is a good place to innovate
  - Size, geography, demographics, leadership
- A complete system reboot is needed, not just a law
  - Donation, tissue, transplant
- Transformational health care change is difficult, especially quickly
  - Need to study what we do, people will be watching

# Preparing for HOTDA

August 2018 -  
February 2019

- Review of Legislation changes.  
Major changes:
  - Presumed consent “Opt-out”
  - Opt-out Registry
  - Mandatory referral
  - Consent process hierarchy
  - Determination of death
  - Donor-Recipient interactions
- Development of detailed project plans to **reboot** donation programs (LoL/CCOD, RTB, MOTP)

## Organ Donation Program, LoL/CCOD plans:

- More co-ordinators, Donor Coordinators to have regional responsibilities
- Establish Donor Physicians across province
- Province wide DCD in conjunction with MOTP
- Increase QA/QI support
- Establish Education Lead Role (MD)
- Create Family Support Liaison position
- IT Support (database)
- Chart Audit Process Revision



# Preparing for HOTDA

August 2018 -  
February 2019



- Review of Legislation changes.
- Development of detailed project plans to reboot donation programs (LoL/CCOD, RTB, MOTP)

April 2019

- HOTDA introduced in Legislature
- 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> readings
- few amendments made
- Unanimous passage in Legislature
- National Media coverage

# HOTDA: Changes to Legislation

## Current Legislation (1989): Human Tissue Gift Act

- Opt-in Registry
- No mandatory referral
- Consent common-law not recognized
- No reporting to CEO/DHW
- Donors and Recipients anonymity required
- Death “as per medical practice”

## Bill 133 (2020): Human Organ & Tissue Donation Act

- Opt-out Consent
- Mandatory referral
- Consent common-law recognized
- Report to NSHS/IWK CEO and DHW
- Permits identifiable interactions between Donor families and Recipients
- Death determination clarified

# HOTDA NSHA / DHW Steering Committee formed

May 2019

- DHW & NSHA Leadership (Lisa Grandy, Nancy MacLeod, Vickie Sullivan)
- System wide updates: Establish working groups, oversee implementation, resolve implementation issues, establish oversight
- Measurement and Evaluation: KPI, public reporting of KPI, oversee finances
- Information and Communication: Methodology for reporting, WG engaged with Comms
- Working Groups: Registry, Marketing/Comms, Legal, IT/Data, LoL, CCOD, MOTP, RTB
- Results Framework workshop

# HOTDA NSHA/DHW Steering Committee

May 2019  
present

- Meeting q4 weeks as a committee, subcommittees meet as needed
- Timeline for proclamation / enactment
  
- Major issues
  - Evaluation / implementation strategy ( with NSHA group)
  - Opt out registry (MSI registry / contractual limits)
  - Communication (survey then strategy)

# HOTDA NSHA Steering Committee formed

May 2019-  
present

- Operational priorities; turn a law into a better system
- LoL / RTB / MOTP / NSHA (IT, Comm) participation
- Admin and clinical reps
  
- Meet q2 weeks
  
- Major challenges
  - HR recruitment of talent (IT, clinical, project manager)

# Preparing for HOTDA: opportunity knocks

April 2018 - August 2019

- Finish program proposals
  - LoL/CCOD
  - MOTP
  - RTB
  - Opt-out Registry
- Treasury Board Approval

June 2019

- Health Canada Project
  - Letter of Intent (10d)
  - Proposal submitted (10d)
  - 3 Activities:
    - Donation system performance
    - Presumed consent around the world
    - Detailed opinion survey (Public, Marginalized Groups, Health Professionals)

# Health Canada (HC) Project

2018-2019

Ongoing discussions with clinical community (Health Canada and Canadian Blood Services, OPO's)

Funding opportunity through Health Canada for system enhancement

July 2019

Health Canada Project proposal submitted

- Letter of intent
- Proposal submitted
- Donation system performance
- Review of presumed consent (worldwide)
- Detailed survey opinion (public, marginalized groups, professionals)

August 2019

- Health Canada Project Proposal approved
- Confirmation of funding

# Health Canada (HC) Project

Aug 2019

Steering committee recruited  
(NSHA, CDTRP, CBS, Trans Que)

Activity 1

system performance

Activity 2

PC international / legal / ethics

Activity 3

knowledge / attitudes  
marginalized groups / social media influence

Sept 2019

potential activity leads are identified, potential projects are discussed

TOR for steering committee

Preliminary budget

NS research community expertise and interest

Oct 2019

F2F in Banff

TOR finalized  
data sharing  
authorship

HC budgeting  
process update

Project manager  
posting

Activity leads  
confirmed

recruit working groups



# Immediate priorities

- Coordinated (NSHA DHW) communications plan developed
- IT needs for LoL/ RTB/ MOTP clarified
- Opt out registry established
- Education strategy developed and implemented (professional and public)
- Recruitment of key personnel/ training of personnel
- HC projects...