Towards Ontario Massive Hemorrhage Protocol (MHP)

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September 22, 2018
GHEST Symposium, Hamilton
Disclosures

• I do not have any relevant conflicts of interest
Outline

• Background
  – What is a massive hemorrhage?
  – What is a massive hemorrhage protocol and why is it important?
• What is the current state in Ontario?
• How are we developing the provincial protocol?
MASSIVE HEMORRHAGE AND MASSIVE HEMORRHAGE PROTOCOL
What is a Massive Hemorrhage?

• No widely accepted universal definition:
  – 10 units in 24 hrs, 6 RBC in 4 hours, etc.
  – Amount and rate of bleeding as well as likelihood of being able to rapidly achieve hemostasis

• Rare, complex and high stress medical scenario

• Associated with a high mortality rate
What is a Massive Hemorrhage?

- Massive hemorrhage may occur in the context of:
  - Trauma
  - Post-partum
  - Cardiovascular event (ex. ruptured abdominal aortic aneurysm)
  - Acute upper GI bleeding
  - Surgical complication
What is a Massive Hemorrhage Protocol (MHP)?

• Protocol, systematic clinical workflow, algorithm, integrated care pathway

  – Aim (7 R’s):
    • Right health care workers, doing the right things, for right patients, in the right order, at the right time, in the right place, with the right outcome

  – Outcomes:
    • Leads to improved outcomes

What are the Goals of MHP?

• To improve patient outcomes including morbidity and mortality
  – Specific Goals: early source control of bleeding, monitoring of relevant hemostatic and physiological parameters, supportive care and optimal transfusion (reduce overtransfusion, treatment related complications, and wastage of blood components)
  – General Goals: translate best evidence and best practices, standardize care, improve communication and coordination within a multi-disciplinary team
Basic Elements of the MHP: $\text{MHP} = T^7$

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
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<td>1</td>
<td>Triggering</td>
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<td>2</td>
<td>Team (and Communication)</td>
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<td>3</td>
<td>Testing</td>
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<td>4</td>
<td>Tranexamic acid</td>
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<td>5</td>
<td>Temperature</td>
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<td>6</td>
<td>Transfusion</td>
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<td>7</td>
<td>Termination</td>
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</table>
Are There Proven Benefits of MHP?

• MHP implementation is associated with
  – Reduction in mortality, organ failure, post-injury complications
    • independent of what exactly is in the protocol
  – Faster delivery of blood components to patient
  – Not associated with increase in blood component wastage
  – Less blood component utilization (and less cost)
  – Decreased length of hospital stay

Effectiveness of massive transfusion protocols on mortality in trauma: a systematic review and meta-analysis

Table 3  Mortality meta-analysis (random-effects model)

<table>
<thead>
<tr>
<th>Study</th>
<th>OR (95% CI)</th>
<th>Weight (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Riskin et al.</td>
<td>0.29 (0.10–0.80)</td>
<td>9.48</td>
</tr>
<tr>
<td>Cotton et al.</td>
<td>0.32 (0.19–0.52)</td>
<td>16.99</td>
</tr>
<tr>
<td>O’Keeffe et al.</td>
<td>1.10 (0.58–2.14)</td>
<td>14.22</td>
</tr>
<tr>
<td>Shaz et al.</td>
<td>1.10 (0.63–1.88)</td>
<td>16.24</td>
</tr>
<tr>
<td>Simmons et al.</td>
<td>0.75 (0.53–1.05)</td>
<td>19.55</td>
</tr>
<tr>
<td>Dirks et al.</td>
<td>1.21 (0.41–3.61)</td>
<td>8.87</td>
</tr>
<tr>
<td>Sisak et al.</td>
<td>1.30 (0.46–3.68)</td>
<td>9.35</td>
</tr>
<tr>
<td>Sinha et al.</td>
<td>0.77 (0.16–3.75)</td>
<td>5.31</td>
</tr>
<tr>
<td>Pooled OR</td>
<td>0.73 (0.48–1.11)</td>
<td>—</td>
</tr>
</tbody>
</table>

CI, confidence interval; OR, odds ratio.

Fig. 2. Meta-analysis of mortality. CI, confidence interval; OR, odds ratio.
Effectiveness of massive transfusion protocols on mortality in trauma: a systematic review and meta-analysis

Authors’ Conclusions:
• Despite the popularity of MTPs and directives mandating their use in trauma centres, in before–after studies, MTPs have not always been associated with improved mortality.
• Evidence-based standardization of MTPs, improved compliance and analysis of broader endpoints were identified as areas for further research.

<table>
<thead>
<tr>
<th>Author</th>
<th>Hospital LOS</th>
<th>ICU LOS</th>
<th>Ventilator days</th>
<th>Cost savings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Riskin et al.</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Cotton et al.</td>
<td>Significantly reduced</td>
<td>No change</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>O’Keeffe et al.</td>
<td>NR</td>
<td>No change</td>
<td>NR</td>
<td>Considerable</td>
</tr>
<tr>
<td>Shaz et al.</td>
<td>No change</td>
<td>No change</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
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<td>NR</td>
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<td>No change</td>
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<td>NR</td>
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ICU, intensive care unit; LOS, length of stay; MTP, massive transfusion protocol; NR, not reported.
WHAT IS THE CURRENT STATE IN ONTARIO?
Ontario MHP Survey

Survey sent via email
All hospitals in Ontario with a Transfusion Service (n=150)

Data collected
Individual survey responses: 30
Hospitals captured: 52 (35% response rate)

Data collected
Hospitals captured: 97 (65% response rate)

General reminder email sent to all invited participants

End of data collection
Completed surveys: 132
Partially completed surveys: 1
Hospitals that confirmed absence of MHP: 17

- Nov 30, 2017
- Dec 12 & 22, 2017
- Dec 23, 2017 (survey deadline)
- Jan 8-12, 2018
- Jan 12, 2018
- Jan 22, 2018
- Feb 12, 2018

Email was sent to encourage completion of survey
Remaining hospitals were contacted by phone
# Sample Questions

| Hospital Demographics | Do you have a hospital approved MHP?  
|                       | What is the year the current policy was approved? |
| Activation Criteria   | Do you have activation criteria? Are the activation criteria the same for all patients?  
|                       | Who is included in the activation roll-out as a team member? |
| Communication         | How are laboratory results communicated to clinical areas?  
|                       | Are ONLY critical laboratory results called? |
| Blood Work            | How often do you draw a set of blood work during an MHP?  
|                       | Which laboratory tests are routinely drawn? |
| Test Availability     | Which test assays are available on site at your hospital?  
|                       | Do you have targeted resuscitation?  
|                       | What is the total number of Lab staff covering all areas at lowest staffing level? |
| Temperature           | Does your protocol require monitoring of patient temperature?  
|                       | What is the temperature target in Degrees Celsius? |
| Transport Containers  | When RBCs, platelets, plasma & cryoprecipitate are required during an MHP, are they transported in a validated container?  
|                       | Which products are routinely stocked on site in the Transfusion Medicine Laboratory? |
| Transfusion Medicine  | During an MHP and when blood group is unknown, what patients receive O Rh negative RBCs?  
|                       | Do you have predefined component packs that are issued during an MHP?  
|                       | What hemostatic agents are included in the protocol? |
| Quality               | Do you track any quality metrics for MHP? |
Hospital Demographics (n=150)

Units of RBCs transfused in 2017
- Small <5000
- Medium 5000-10,000
- Large > 10,000

Hospitals with a Transfusion Service

Hospitals with an MHP

91% have an MHP

Legend:
- MHP
- No MHP
Test Availability in Hospitals

- Creatinine: 133
- Electrolytes: 133
- CBC: 132
- INR: 131
- Calcium: 129
- aPTT: 128
- Group & Screen: 127
- Lactate: 126
- Blood Gas: 124
- Fibrinogen: 88
- Ionized Calcium: 86
- ROTEM sample: 9
- TEG sample: 2
- Other: 8
Products and Components Routinely Stocked in Hospitals

Products Routinely Stocked on Site in the TML

- PCC (3000IU+): 125
- Frozen Plasma (4+ units): 108
- RBC (all blood groups): 97
- Cryoprecipitate (10+ units): 83
- O Rh-negative RBC: 80
- O Rh-positive RBC: 75
- Recombinant Factor VIII: 58
- Fibrinogen Concentrate (4g+): 48
- Platelets (1-2 units): 44
- Platelets (3+ units): 23
- Frozen Plasma (2+ units): 21
- Pre-labeled trauma stock units: 21
Hospitals with an MHP (n=97)

Protocol Names

- 61% Massive Transfusion Protocol
- 18% Adult Life Threatening Hemorrhage P&P
- 12% Code Red
- 7% Massive Hemorrhage Protocol
- 2% Code Omega
- Other

Other names:
- Adult Life Threatening Hemorrhage P&P
- Massive Bleeding Protocol
- Massive Blood Transfusion
- Massive Hemorrhage Control Protocol (MHCP)
- Massive Transfusion Order Set
- Massive Transfusion & Code Bleed

78% of protocols were implemented or updated in the past 5 years
MHP Activation Criteria

Hospitals with Activation Criteria

- Yes: 85%
- No: 15%

Activation Criteria Included in MHP

- Blood loss volume: 68
- Units of RBC transfused: 58
- Hemodynamic parameters: 31
- Need for uncrossmatched blood: 18
- Need for inotropes & bleeding: 10
- No response to crystalloid & bleeding: 6
- Other: 22
MHP Method of Activation

Method of Activation

- Call to the TML: 76
- Call to locating for 'code' page: 24
- CPOE: 9
- Other: 20

Activation Through Locating

- Silent Page: 13%
- Overhead alert announcement: 87%

Silent page: 3/24 (13%)
Overhead: 21/24 (87%)
Who is Informed of MHP?

Porters deliver blood/lab samples at 62 hospitals (64%)
Communication During MHP

- 90/97 (93%) Yes
- 7/97 (7%) No

Other:
- Prints in patient area
- Lab staff member will communicate
- Point of care
- Hand delivered

Communication of Lab Results to Clinical Areas

- Phone to local extension: 75
- Electronic patient record: 60
- Dedicated MHP phone: 9
- Fax: 1
- Other: 11

Only Critical Lab Results are Called

- Yes: 94%
- No: 7%

90/97 (93%) Yes
7/97 (7%) No
Laboratory Investigations During MHP

Blood Work Drawn During an MHP

- At discretion of physician: 37%
- At predefined intervals (e.g., hourly): 17%
- Beginning and end of activation and at predefined intervals: 10%
- At start of each pack: 3%
- Beginning and end of activation: 2%
- None, patient receives formula resuscitation: 0%
Urgent Anticoagulant Reversal Plan

Specified Reversal Plan for Patients on Anticoagulant/Antiplatelet Agents

57/97 (59%) Yes
40/97 (41%) No
Emergency Release RBC

Patients Receive O Rh-negative when Blood Group is Unknown

- Yes: 47/132 (36%)
- No: 85/132 (64%)

Patients that Receive O Rh-negative RBC

- Females <45: 51
- Patients with history of anti-D: 23
- Females <50: 17
- Children: 12
- Women of child bearing age: 9
- Females <46: 4
## Predefined Component Packs

<table>
<thead>
<tr>
<th>Pack</th>
<th>Units of RBC</th>
<th>Units of Plasma</th>
<th>Units of Platelet</th>
<th>Units of Cryoprecipitate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Average: 4.16 Mode: 4</td>
<td>Average: 2.26 Mode: 4</td>
<td>Average: 0.28 Mode: 0</td>
<td>Average: 0.19 Mode: 0</td>
</tr>
<tr>
<td></td>
<td>Median: 4</td>
<td>Median: 2.5</td>
<td>Median: 0</td>
<td>Median: 0</td>
</tr>
<tr>
<td>2</td>
<td>Average: 3.02 Mode: 4</td>
<td>Average: 3.43 Mode: 4</td>
<td>Average: 0.85 Mode: 1</td>
<td>Average: 2.34 Mode: 0</td>
</tr>
<tr>
<td></td>
<td>Median: 4</td>
<td>Median: 4</td>
<td>Median: 1</td>
<td>Median: 0</td>
</tr>
<tr>
<td>3</td>
<td>Average: 3.68 Mode: 4</td>
<td>Average: 3.24 Mode: 4</td>
<td>Average: 1.18 Mode: 1</td>
<td>Average: 1.32 Mode: 0</td>
</tr>
<tr>
<td></td>
<td>Median: 4</td>
<td>Median: 4</td>
<td>Median: 1</td>
<td>Median: 0</td>
</tr>
<tr>
<td>4</td>
<td>Average: 3.28 Mode: 4</td>
<td>Average: 2.69 Mode: 4</td>
<td>Average: 0.81 Mode: 1</td>
<td>Average: 2.19 Mode: 0</td>
</tr>
<tr>
<td></td>
<td>Median: 4</td>
<td>Median: 2</td>
<td>Median: 1</td>
<td>Median: 0</td>
</tr>
<tr>
<td>5</td>
<td>Average: 3.83 Mode: 4</td>
<td>Average: 3 Mode: 4</td>
<td>Average: 0.78 Mode: 1</td>
<td>Average: 0.87 Mode: 0</td>
</tr>
<tr>
<td></td>
<td>Median: 4</td>
<td>Median: 4</td>
<td>Median: 1</td>
<td>Median: 0</td>
</tr>
</tbody>
</table>
Targeted Transfusion Therapy

### Hospitals with Targeted Resuscitation

- **Yes**: 36%
- **No**: 64%

### Targeted Resuscitation

<table>
<thead>
<tr>
<th></th>
<th>PLT x 10⁹/L</th>
<th>INR (s)</th>
<th>Fibrinogen (g/L)</th>
<th>Hb (g/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mode</strong></td>
<td>50</td>
<td>1.8</td>
<td>1.5</td>
<td>70</td>
</tr>
<tr>
<td><strong>Median</strong></td>
<td><strong>50</strong></td>
<td><strong>1.8</strong></td>
<td><strong>1.5</strong></td>
<td><strong>70</strong></td>
</tr>
<tr>
<td><strong>STD</strong></td>
<td>19.51</td>
<td>0.25</td>
<td>0.33</td>
<td>11.65</td>
</tr>
</tbody>
</table>
Utilization of Hemostatic Agents

- **rFVIIa**: Yes 4%, No 96%
- **Fibrinogen Concentrate**: Yes 13%, No 87%
- **PCC**: Yes 14%, No 86%
- **Tranexamic acid**: No 30%, Yes 70%
Quality Metrics Tracked

Hospitals that Perform Multidisciplinary Reviews of MHPs

- Yes: 68%
- No: 32%

- 66/97 (68%) Yes
- 31/97 (32%) No

Hospitals that Track Quality Metrics for MHP

- Yes: 69%
- No: 31%

- 30/97 (31%) Yes
- 67/97 (69%) No
Quality Metrics Tracked

- Activations resulting in blood wastage: 18
- MHP activated as per pre-specific criteria: 16
- Group & Screen sent at baseline: 15
- Blood delivered w/n <15 mins of activation: 14
- MHP discontinued w/n 1h of last component or patient's demise: 14
- 36° C or higher maintained: 13
- Patients w/ Hemorrhage Panel sent at baseline: 13
- Fibrinogen >2 maintained during protocol: 11
- Temp. monitored & hypothermia managed: 11
Current State: Ontario

- MHPs have not been implemented in a third of transfusion services
- Different names
- Different methods of activation: activation by CPOE, written vs. verbal order, code (silent vs. overhead)
- Different communication plans
- Different activation criteria
- Different team members
- Different contents of packs and different transfusion goals
- Different transfusion rules
- Different monitoring – which labs and when
- Different supportive care (ex. TXA)
Current State: Ontario

• Different
  • Someone is not getting standard of care
  • Staff confusion -> inefficiency, suboptimal performance
    – Trainees, doctors, nurses, RTs, MLTs who work/train in multiple hospitals
    – No ability to know how you are doing compared to peers

• Conclusion:
  • There is significant heterogeneity in MHPs which could be addressed by a standardized province-wide protocol tailored to the size of each hospital
Without Provincial MHP
TOWARDS PROVINCIAL MHP
Towards a Provincial MHP

• Many jurisdictions have moved to a single protocol
  – Countries: Singapore (5.3 million, 716.1 km)
  – Provinces: Manitoba, Labrador and Newfoundland
  – Regions: Alberta Health Services, EORLA

• It is doable and associated with good outcomes
Provincial MHP Wishlist

• Must be publically available and publically funded
• Must be MOH endorsed
• Development must include a multidisciplinary team of experts
• Must be based on the most up-to-date evidence and best practices
• Must take into account diversity of patients and institutions within Ontario
• Must be regularly reviewed and updated
What Should Be in a Tool Kit?

• Background/evidence
• Policy and procedure (clinical areas vs laboratory, big vs. small hospitals)
• Implementation tools
  – Records, checklists, etc.
  – Educational and competency assessment materials
• Quality assurance and improvement tools
  – audit sheets, quality indicators, etc.
How Do We Get There?

1. University of Toronto transfusion medicine rounds on MHP
2. Survey of Ontario hospitals on MHP (to establish current state)
3. MHP meeting (at the Ontario Transfusion Committee Forum)
4. Delphi technique to develop contents for the provincial MHP
   - 1st round – pre-MHP meeting
   - 2nd round – after MHP meeting
   - 3rd and subsequent rounds – if necessary
5. Development of provincial MHP and supplementary materials
6. External review and revisions
7. Dissemination and implementation of provincial MHP
8. Survey of Ontario hospitals on MHP (to establish post state)
The Oracle of Delphi

The Delphi Technique

• Developed by Project RAND during the 1950-1960s
  – an organization formed post World War II to connect military planning with research and development decisions

• Systematic, interactive forecasting method which relies on a panel of experts
  – 4 methodological features
    (1) a group of experts, called ‘panelists’, is questioned about the issue of interest
    (2) the process is anonymous in order to avoid social pressure and conformity to a dominant view (bandwagon effect)
    (3) the procedure is iterative in nature, comprising several rounds of enquiry
    (4) the design of subsequent rounds is informed by a summary of the group response of the previous round
  – During the process the range of the answers decreases and the group converges towards the "correct" answer
  – The process is stopped after a predefined stop criterion (e.g. number of rounds) and the mean or median scores of the final rounds determine the results

Why Delphi?

• The Delphi technique is a relevant source of evidence in health care research, especially if:
  – Evidence is needed to be drawn outside the gold standard RCTs and the aim is to build systematic consensus in order to resolve uncertainty about a clinical question or a concept of care
  – Quantitative methods are unlikely to yield results that can be successfully implemented in practice
Panelists

• 37 members: invited, multidisciplinary, voluntary
  – Physicians
    • Anaesthetists, trauma and general surgeons, OB/GYN, hematologists, transfusion medicine physicians, ER physicians, pre-hospital care physicians, and critical care physicians
  – Nurses
  – Technologists – transfusion and coagulation
  – Patient
  – Blood supplier representatives
Materials for the Panelists

• Letter explaining the role, technique, time commitment, etc.
• Evidence (pdfs of MHP original papers) - in order to standardize the knowledge base of panelists
Methods

• Research team developed 43 statements and 8 quality metrics to be evaluated by panelists via electronic survey (LimeSurvey)

• Surveys are not anonymous, however, responses and comments by the panelists will be anonymized prior to presentation to the entire panel

• Each statement is rated on a 7 point scale from “definitely should not” to “very important” to include
  – opt out option (“unable to answer as outside of my area of expertise”)
  – comment box
## MHP Forum, Day 1

**Friday April 20, 2018**

*DoubleTree by Hilton Toronto Downtown*

108 Chestnut Street, Toronto

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<th>Topic</th>
<th>Time</th>
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</thead>
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<td><strong>Breakfast &amp; Registration</strong></td>
<td><strong>0730-0800</strong></td>
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<tr>
<td>Dr. Jeannie Callum</td>
<td>Welcome and opening remarks</td>
<td>0800-0815</td>
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<tr>
<td>Dr. Barto Nascimento</td>
<td>Question/answer period</td>
<td>0815-0830</td>
</tr>
<tr>
<td>Dr. Jeannie Callum</td>
<td>MHP: why we need a provincial plan</td>
<td>0830-0845</td>
</tr>
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<td>Question/answer period</td>
<td>0845-0900</td>
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<tr>
<td>Dr. Andrew Petrosoniak</td>
<td>MHP: results of the provincial survey</td>
<td>0900-0915</td>
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<td>Dr. Andrew Petrosoniak</td>
<td>MHP: protocol initiation criteria</td>
<td>0930-0945</td>
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<tr>
<td><strong>Foyer</strong></td>
<td><strong>Break</strong></td>
<td><strong>0945-1000</strong></td>
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<tr>
<td>Dr. Russell MacDonald</td>
<td>MHP: pre-hospital activation</td>
<td>1000-1015</td>
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<td>1015-1030</td>
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<td>MHP: team members</td>
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<td>Dr. Katerina Pavenski</td>
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<td>Question/answer period</td>
<td>1115-1130</td>
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<tr>
<td>Ms. Lee Barratt</td>
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<td>1130-1145</td>
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<td>Question/answer period</td>
<td>1145-1200</td>
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<td><strong>Lunch</strong></td>
<td><strong>1200-1245</strong></td>
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<td>Dr. Michelle Sholzberg</td>
<td>MHP: standard lab test targets</td>
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<td>1300-1315</td>
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<tr>
<td>Dr. Sandro Rizoli</td>
<td>MHP: viscoelastic testing role and target</td>
<td>1315-1330</td>
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<tr>
<td>Dr. Katerina Pavenski</td>
<td>MHP: blood bank protocol large hospital</td>
<td>1530-1545</td>
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<tr>
<td>Dr. Andrew Petrosoniak</td>
<td>Question/answer period</td>
<td>1545-1600</td>
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</table>
# MHP Forum, Day 2

**Saturday April 21, 2018**

**0900-1400**

**DoubleTree by Hilton Toronto Downtown**

**108 Chestnut Street, Toronto**

**Program focusing on building a case for a Provincial Massive Hemorrhage Protocol**

<table>
<thead>
<tr>
<th>Speaker</th>
<th>Topic</th>
<th>Time</th>
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<tbody>
<tr>
<td>Co-Chairs</td>
<td>Welcome and Project overview</td>
<td>0830-0900</td>
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<td></td>
<td>Initiation / Activation criteria – clarifying question?</td>
<td>0900-0915</td>
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<td>• Panel Discussion / Vote</td>
<td>0915-0945</td>
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<td>MHP team - clarifying question?</td>
<td>0945-1015</td>
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<td>• Panel Discussion / Vote</td>
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<td>MHP Labs - clarifying question?</td>
<td>1015-1045</td>
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<td>• Panel Discussion / Vote</td>
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<td></td>
<td><strong>Break</strong></td>
<td>1045-1100</td>
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<td>MHP transfusion goals - clarifying question?</td>
<td>1100-1130</td>
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<td>• Panel Discussion / Vote</td>
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<td>MHP supportive care/DCR- clarifying question?</td>
<td>1130-1200</td>
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<td>• Panel Discussion / Vote</td>
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<td>MHP quality metrics - clarifying question?</td>
<td>1200-1230</td>
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<td>• Panel Discussion / Vote</td>
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<td><strong>Lunch</strong></td>
<td>1230-1300</td>
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<td>Provincial rollout: Implementation, dissemination, education</td>
<td>1300-1330</td>
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<td>Monitor for quality: how to measure impact/uptake and re-assess performance</td>
<td>1330-1400</td>
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<td><strong>Adjourned</strong></td>
<td>1400</td>
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Methods

• Rounds of surveys
  – 1\textsuperscript{st} round: 1 month in advance of the MHP forum
  – 2\textsuperscript{nd} round: after day 2 of the forum
    • FTF presentation and discussion of the 1\textsuperscript{st} round results
  – 3\textsuperscript{rd} and subsequent rounds (if necessary)

• Analysis
  – Quantitative: median score calculated for each statement and compared against a pre-established criteria
  – Qualitative: comments are collated and summarized for the panelists to inform the subsequent rounds
  – Rounds may be used to add, remove or modify the statements
  – Statements will form a framework for the MHP
The Next Steps?

- Complete Delphi exercise and start working on the toolkit
Conclusions

• MHP is an algorithm to manage massively bleeding patients
• MHP is associated with better patient outcomes
• There is a significant heterogeneity in MHP protocols across Ontario
• We are working on the provincial plan