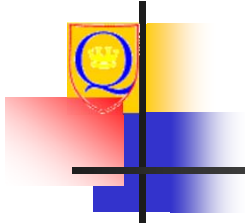


IVIG Utilization Management Strategy in 2016



Optimizing and Sustaining IVIG use in Ontario **“The Road We’ve Travelled Since 2012”**

Dr. Lois Shepherd, Chair, IVIG Advisory Panel
Transfusion Committee Forum
April 8, 2016



Objective

- To provide an update on the IVIG Utilization Management Strategy (“IVIG Strategy”)

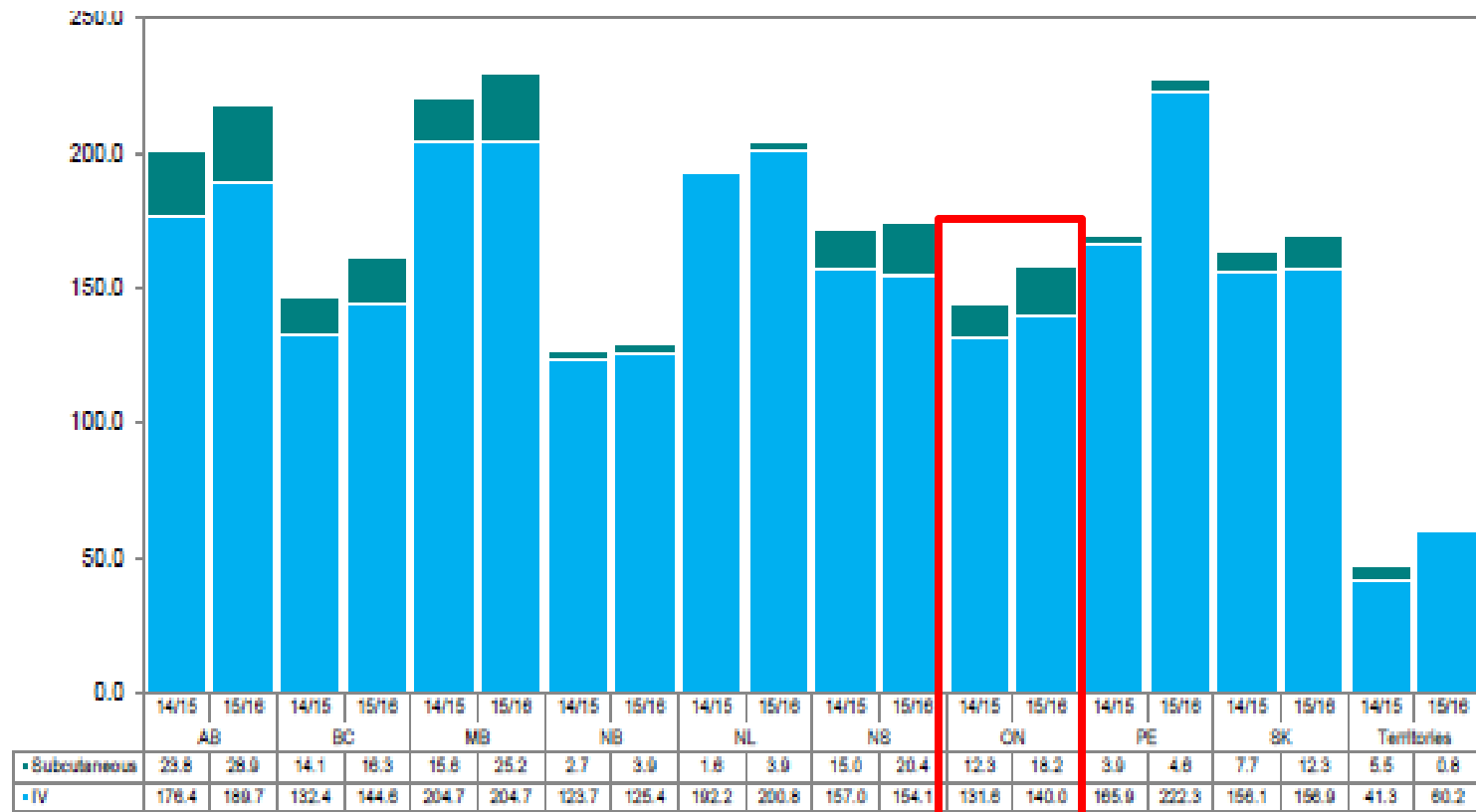
- To provide an overview of the new Immune Globulin Screening Pilot (IGSP)

- Presented in collaboration with:
 - IVIG Advisory Panel (“IVIGAP”)
 - Ministry of Health and Long-Term Care (“MOHLTC” or “the ministry”)
 - Ontario Regional Blood Coordinating Network (“ORBCoN”)

About IG: Utilization

IG Provincial Comparison by Population 2014/15 vs 2015/16*

(*total grams per 1,000 population; 2015/16 forecasted based on Q3 year-to-date actual)

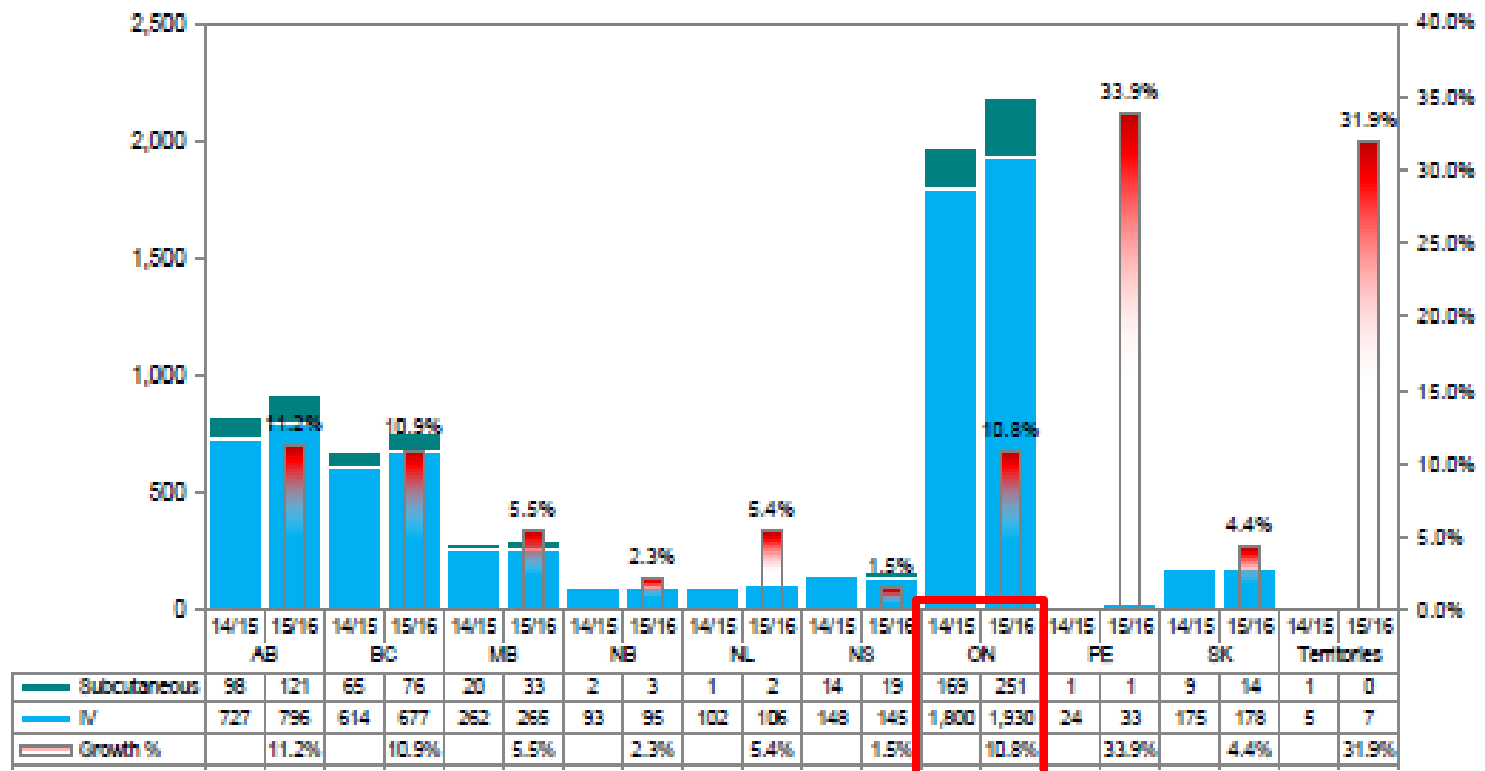


- Ontario has one of the lowest utilization rates among other provinces/territories

About IG: Utilization cont'd...

IG Provincial Comparison 2014/15 vs 2015/16*

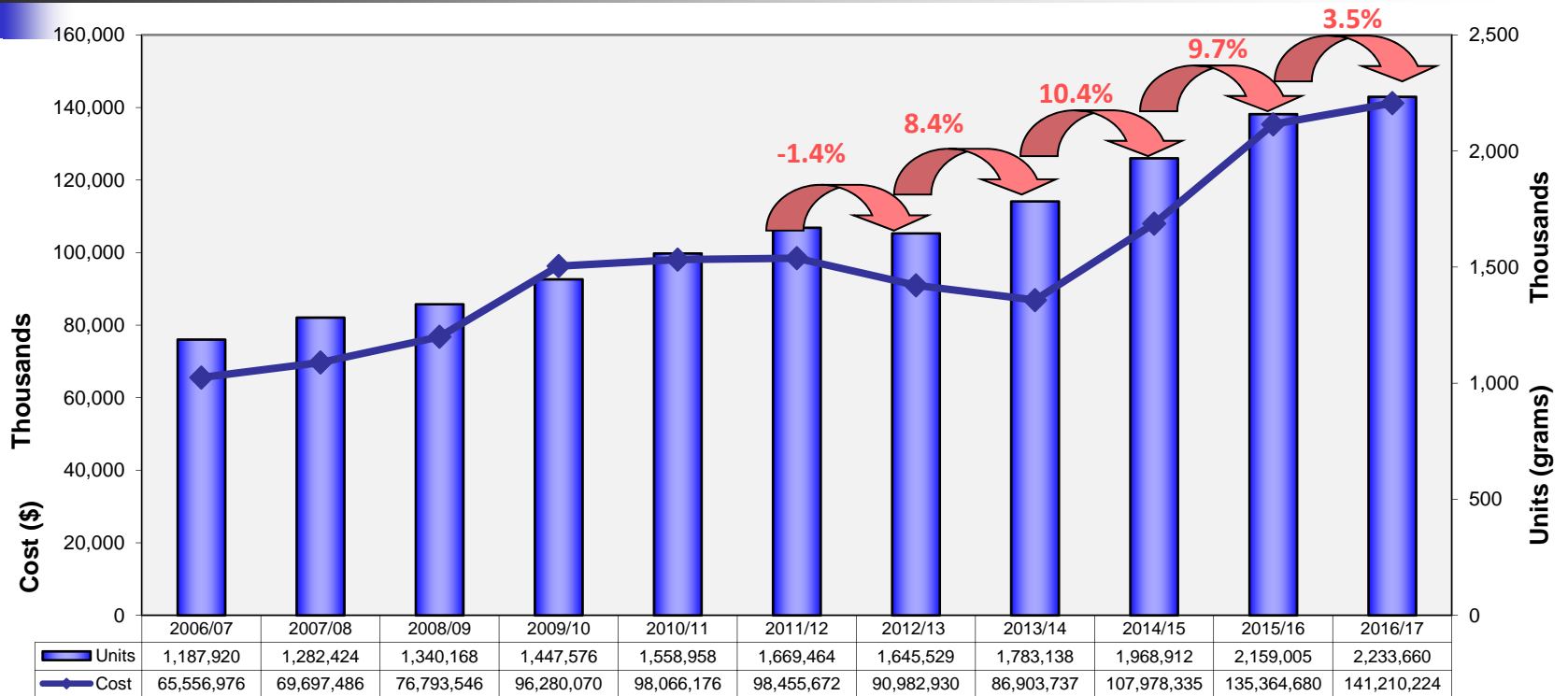
(*total thousands of grams by province/territory; 2015/16 forecasted based on Q3 year-to-date actual)



- From 2014/15 to 2015/16, Ontario's use has increased by 10.8%

About IG: Utilization cont'd...

IG Annual Use and Expenditures in Ontario 2006/07 to 2016/17



- Ontario's IG use and expenditures have increased from about **1.2M units** (\$65.6M) in 2006/07 to **2.2M units** (\$135.4M) in 2015/16*; an average yearly increase of about **7.0%**
- An overall increase of **83.3%** in units and **106.4%** in costs in nine years

*Figures for 2015/16 and 2016/17 are forecasted.



IVIG Strategy: Key Components

- 1. Adherence to Ontario IVIG Utilization Management Guidelines (“Ontario Guidelines”)**
- 2. Implementation of MOHLTC IVIG Request Form**
- 3. Review/Approval for Indications Not on Request Form**
- 4. Dosing Through Adjusted Body Weight**
- 5. Evaluating Clinical Outcomes and Need for Assessment**
- 6. No Outdating**
- 7. Audit**

IVIG Strategy: History



2012/13

- IVIG Strategy Launch
- Provincial IVIG utilization audit completed

2013/14

Key concerns:

- Scope of practice
- Dosing (use of dose calculator; adjusting for weight) and new indications

2014/15

Key concerns:

- Expertise of screeners
- Need reassessments to ensure chronic IVIG treatment continues to be effective

2015/16

- SCIG Home Infusion Kit completed
- Compliance audit completed



IVIG Strategy: Current Status



IVIIG Strategy: Guidelines

Revision of Ontario Guidelines

- IVIGAP Specialty Members led Working Groups (“WG”) to update guidelines including:
 - Identifying IVIG as 1st, 2nd, 3rd line treatment; alternative treatment options
 - Identifying intervals for reassessment to confirm treatment continues to be effective and minimum effective dose is prescribed
 - Identifying criteria to be met for treatment to be considered effective at reassessment
- WGs completed revisions; revisions sent to top user hospitals for review
- Next step: send to respective Associations for endorsement
- Target publication date delayed from December 2015 to Summer 2016; Immunology and Dermatology expected in late 2016

Dermatology

Hematology

Immunology

Infectious
Disease

Neurology

Rheumatology

Solid Organ
Transplant

IVIG Strategy: Request Form

Revision of the MOHLTC IVIG Request Form

- Development of an online request form and database to facilitate completion of the Request Form and to perform compliance and utilization audits
 - Phase I: 2-3 month pilot with 3-6 hospitals; manual data entry by ORBCoN (completed)
 - Phase II: direct web-based data entry by pilot hospitals
 - Phase III: implementation of online form and web-based data entry
- Currently on hold due to finalization of guideline revisions and development of a new screening pilot

The screenshot displays the ORBCoN IVIG Tracking web application. At the top, the ORBCoN logo (Ontario Regional Blood Coordinating Network) is visible on the left, and user information (Users Online: 1, Welcome Leslie Young, ORBCoN Username: Leslie, My Profile) is on the right. The main heading is "ORBCoN IVIG Tracking". Below this, a navigation bar includes links for Home, Data Entry, Modify Data, Track Patient, Query Data, Select Random, Statistics, Charts, Contact, and Administrator. The "Data Entry" link is highlighted. The main content area is titled "Data Entry & Modification" and features a search bar with a red "X" icon and a magnifying glass icon. Below the search bar, there is a "Print" link and a "MOHLTC Request Form" section. The "MOHLTC Request Form" section contains a "Location" dropdown menu, a "Select Location" button, a "Patient ID" input field, and a "Continue" button.

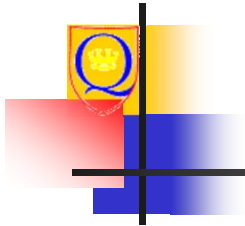
IVIIG Strategy: Dosing

Continued Messaging Related to Dosing

- Use minimum effective dose
- Dose Adjustment for Obesity
- Dose Verification
- Dose should not be changed without the ordering physician's knowledge/consent
- No plan to develop a dose calculator for pediatric/adults < 5 Feet
- ❖ *Use of the dose calculator can help to catch near misses of overdosing with IVIG*

The screenshot shows a mobile application interface for a 'Dose Calculator'. The top status bar displays 'Bell', signal strength, Wi-Fi, '1:14 PM', and '91%' battery. The app title 'Dose Calculator' is in a red header. Below it, the 'Ideal Weight Calculator' section includes: Gender (male), Height (180 cm), and Weight (200 lbs). It displays 'Ideal Body Weight' as 75.0 kg and 'Dosing Weight' as 81.3 kg. The 'IVIg Dose Calculator' section includes: Dosing (0.4), IVIg Dose (50.0 g), and IVIg Dose (rounded) (50.0 g). The bottom navigation bar has three icons: 'IVIg Home', 'Dose Calculator', and 'Settings'.

IVIG Strategy: Mobile Friendly App



IVIG Home

Browse by Specialty

Browse by Condition

| | |
|-----------------------------|------|
| Dermatology | 3 > |
| Hematology | 15 > |
| Immunology | 2 > |
| Infectious Diseases | 2 > |
| Neurology | 11 > |
| Rheumatology | 2 > |
| Solid Organ Transplantation | 3 > |

Dose Calculator



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IVIG Strategy: No Expiry

- IG Redistribution from 2013/14 to 2015/16

| Fiscal Year | Units Redistributed (IU) | Cost Avoidance (\$) | Cost to Redistribute (\$) | CBS Cost per Unit (\$) |
|-------------|--------------------------|---------------------|---------------------------|------------------------|
| 2013/14 | 477 | 26,351 | 330 | 55.29 |
| 2014/15 | 2,228 | 106,628 | 962 | 47.85 |
| 2015/16 | 1,833 | 93,970 | 154 | 51.28 |
| Total | 4,538 | 226,949 | 1,446 | |

Note: Figures have been rounded.

IVIG Strategy: Audit

Retrospective Compliance Audit

(led by McMaster University – 4 centres)

- To determine case mix for new IVIG requests
- To authenticate information provided on the Request Form
- To assess clinical effectiveness of IVIG
- Jan –Dec 2014
- 179 patients assessed

52% did not meet criteria for IVIG use

19% of cases had a discrepancy between diagnosis on MOHLTC IVIG Request Form & chart diagnosis

34% noted only a subjective improvement

32% did not document any indication of efficacy after IVIG administration

Most Common Indications

24% Immune Thrombocytopenia

20% Secondary Immune Deficiency

Most frequent users:
38% hematologists
11% neurologists

47% did not dose to ideal body weight

24% of cases were for "Other" Indications

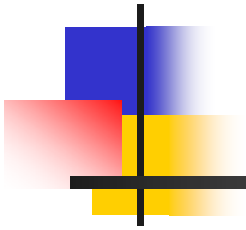
IVIG Strategy: Next Steps



- Variations in dosing and screening practices
- 13-15% of use is for Unapproved Indications
- Continued unsustainable growth

- Utilization in accordance with provincial guidelines
- Compliance with completing MOHLTC IVIG Request Form
- Consistent, standardized screening process
- Documentation for diagnostic criteria and proof of efficacy

Immune Globulin Screening Pilot (IGSP)





IGSP: Overview

Objectives

- Determine if a standardized and rigorous screening model will reduce inappropriate use
- Improve patient outcomes by ensuring treatment continues to be effective and that minimum effective dose is being applied
- Gain a better understanding of factors contributing to increases in IG utilization



IIGSP Background

- IGSP Working Group, a WG of the IVIGAP, convened in Dec 2015 to develop and facilitate implementation of the IGSP;
- Membership includes five neurology specialists /IVIGAP
- Leverage ministry's Exceptional Access Program (EAP) infrastructure to receive, adjudicate, document and reply to requests
- Separate program with dedicated staff to ensure appropriate turn-around-times (TAT)
- Provides standardized, external, arm's length review;
- Familiar to ordering physicians



IGSP: Overview cont'd...

■ Scope

- Applies to all hospitals that order/issue IG
- Will screen all requests for IG for medical conditions within Neurology:
 - New and Renewal requests
 - Approved Indications, Recommended Option and Unapproved Indications
 - Rolled out as a six-month pilot
- All other requests, outside the pilot, will continue to follow the existing process
- Pending evaluation in winter 2016/17, the pilot may be stopped, amended, or expanded



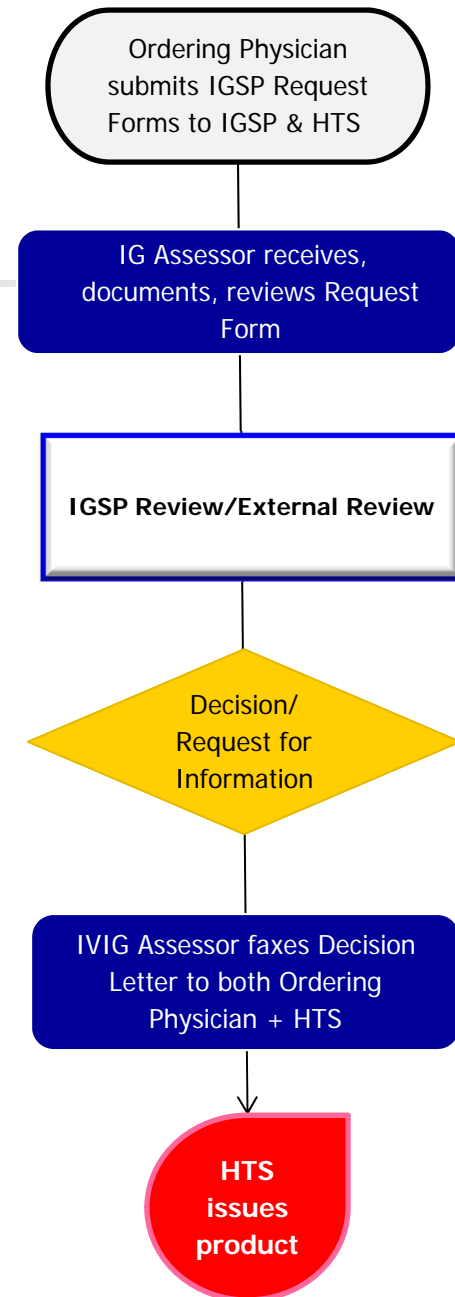
IGSP: Overview cont'd...

Key Components

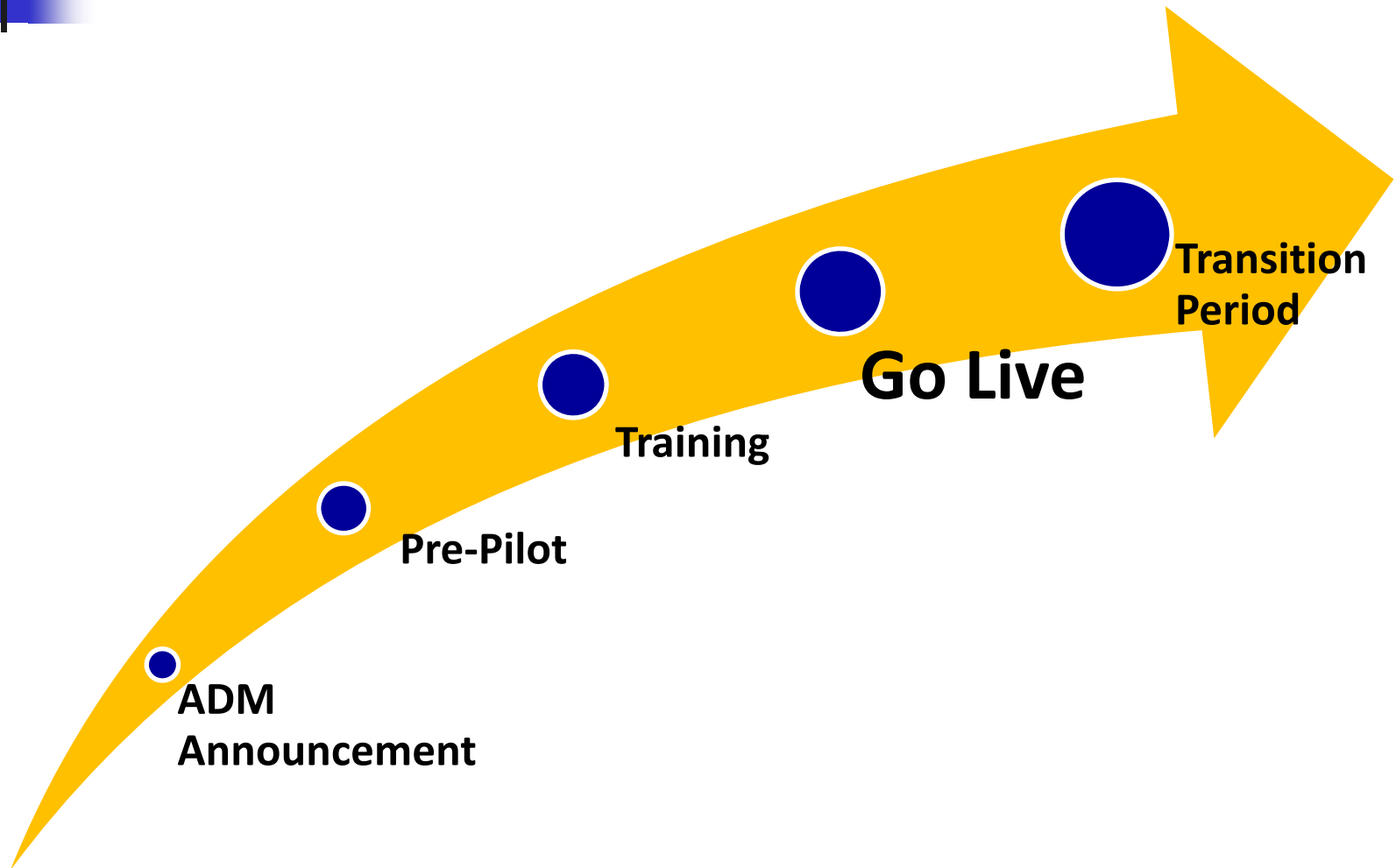
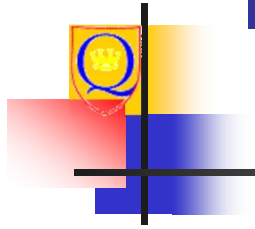
- IGSP Request Form *must* be used; all fields must be complete
- New/renewal requests for approved indications with standard dose/duration screened by the IGSP Assessor (target TAT 24 hours)
- Requests that deviate from Ontario Guidelines go for external review by a neurologist/ neuromuscular specialist (target TAT 72hours)
- Outcome Questionnaire must be completed when submitting a renewal request
- Hospital Transfusion Services (HTS) cannot issue IG without IGSP Approval Letter
- Process for urgent requests (e.g. IG needed within 12 hours, or on weekends)
- Mechanism for random audits will be developed to monitor compliance

IGSP: Overview

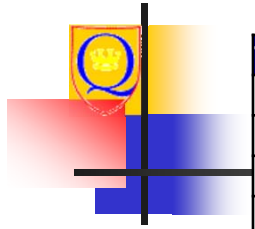
- Ordering Physician (OP) submits IGSP Request Form to IGSP and HTS
- Send to both IGSP Dedicated Fax Line - *similar to how requests are submitted to EAP for drugs* - and HTS
- If IGSP Request Form is incomplete, IG Assessor will send a letter to OP requesting missing information
- IGSP Assessor sends a decision letter to both OP and HTS
- If request is approved, HTS will issue IG upon receiving Order Form
- The MOHLTC IVIG Request Form will not list neurological medical conditions and will direct OPs to new IGSP Request Form



IGSP: Key Milestones



IVIG Advisory Panel



| Title | First | Last | Organization |
|--|----------|------------------------|---|
| Dr. | Lois | Shepherd, <i>Chair</i> | Kingston General Hospital |
| Dr. | Yulia | Lin, <i>Vice Chair</i> | Sunnybrook Health Sciences |
| Ms. | Jennifer | Davis | CBS Plasma Products and Services |
| Dr. | Anthony | Giulivi | The Ottawa Hospital |
| Ms. | Nancy | Heddle | McMaster University Transfusion Research Program |
| Dr. | Lani | Leiberman | University Health Network |
| Ms. | Doris | Neurath | The Ottawa Hospital |
| Dr. | Katerina | Pavenski | St Michaels Hospital |
| Dr. | Elianna | Saidenberg | The Ottawa Hospital |
| Mr. | Peter | Saunders | CBS Plasma Products and Services |
| Dr. | Kathryn | Webert | Canadian Blood Services |
| Dr. | Michelle | Zeller | McMaster University, Hamilton Health Sciences |
| Ms. | Wendy | Owens | Ontario Regional Blood Coordinating Network |
| Ms. | Laurie | Young | Ontario Regional Blood Coordinating Network |
| Ms. | Ramona | Muneswar | Blood Programs Coordinating Office |
| Ms. | Denise | Evanovitch | Ontario Regional Blood Coordinating Network |
| Dr. | Allison | Collins | Ontario Regional Blood Coordinating Network |
| Ad Hoc Specialty Members: Led Guideline Revision Working Groups | | | |
| Dr. | Jeffrey | Schiff | Bone Marrow Transplant, Nephrology, University Health Network |
| Dr. | Neil | Shear | Dermatology, Sunnybrook Health Sciences |
| Dr. | Stephen | Betschel | Immunology, St. Michael's Hospital |
| Dr. | Chaim | Roifman | Immunology, Hospital for Sick Children |
| Dr. | Nick | Daneman | Infectious Disease, Sunnybrook Health Sciences |
| Dr. | Vera | Bril | Neurology, University Health Network |
| Ms | Wilma | Koopman | Neurology, London Health Sciences Centre |
| Dr. | Michael | Melanson | Neurology, London Health Sciences Centre |
| Dr | Pari | Basharat | Rheumatology, London Health Sciences Centre |
| Dr. | Rachel | Shupak | Rheumatology, St. Michael's Hospital |
| Dr. | Jeff | Lipton | Bone Marrow Transplant, |



IGSP Working Group

| Title | First | Last | Organization |
|-------|----------|------------------------|--|
| Dr. | Lois | Shepherd, <i>Chair</i> | Kingston General Hospital |
| Dr. | Yulia | Lin, <i>Vice Chair</i> | Sunnybrook Health Sciences |
| Dr. | Vera | Bril | University Health Network |
| Dr. | Hans | Katzberg | University Health Network |
| Ms | Wilma | Koopman | London Health Sciences and St. Joseph's London |
| Dr. | Michael | Melanson | Kingston General Hospital |
| Dr. | Steve | Baker | Hamilton Health Sciences Centre |
| Dr. | Pierre | Bourke | The Ottawa Hospital |
| Dr. | Kurt | Kimpinski | London Health Sciences and St. Joseph's London |
| Ms. | Laura | Aseltine | London Health Sciences and St. Joseph's London |
| Ms | Doris | Neurath | The Ottawa Hospital |
| Ms. | Denise | Evanovitch | Ontario Regional Blood Coordinating Network |
| Ms. | Wendy | Owens | Ontario Regional Blood Coordinating Network |
| Ms. | Sheena | Scheuermann | Ontario Regional Blood Coordinating Network |
| Ms. | Laurie | Young | Ontario Regional Blood Coordinating Network |
| Ms. | Ramona | Muneswar | Ministry of Health and Long-Term Care |
| Ms | Margaret | Wong | Ministry of Health and Long-Term Care |

Thank you

