

# The Frozen Plasma Audit

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Then and Now

2008 and 2013

Lois Shepherd, MDCM

TC Symposium, February 24, 2014



# Outline and Objectives

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- Background
- A comparison of the FP Audits in 2008 and preliminary data from the repeat 2013 audit
- Use of Prothrombin Complex Concentrates
- Impact of ORBCoN's FP Toolkit on ordering practices in Ontario
- How best to use this information going forward?



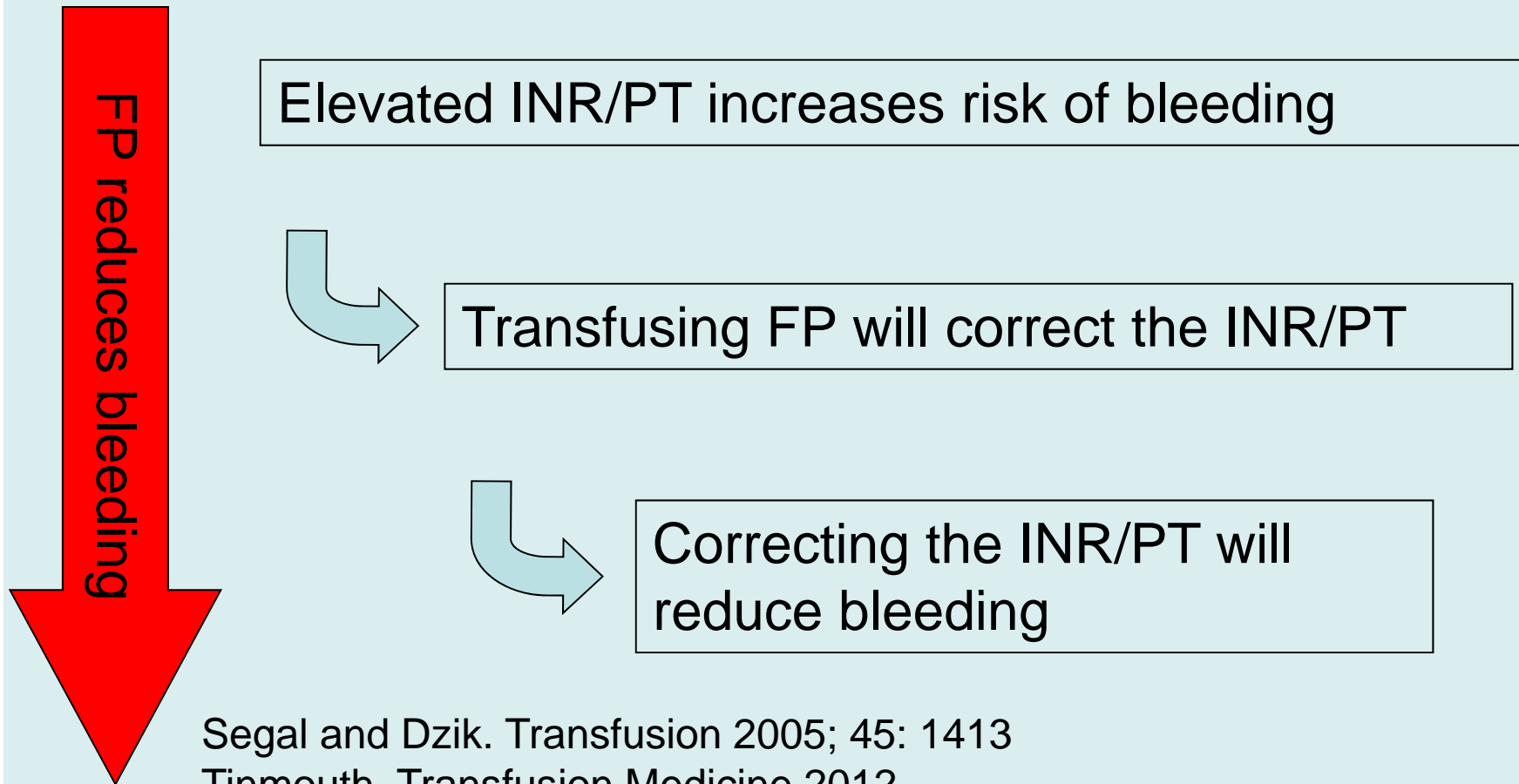
# Flavors of Frozen Plasma

- Fresh Frozen Plasma (FFP)
  - Frozen within 8 hours of collection
  - Minimum factor VIII level of 0.7 IU/mL
  - Approximately 1 IU/mL of other factors
- Frozen Plasma 24
  - Frozen within 24 hours of collection
  - Decreased factor VIII levels
- Thawed plasma
  - Thawed FFP or FP 24
  - Kept up 1-5 days at 4°C
  - Decreased levels of factor V and VIII



# Paradigm for Frozen Plasma Use

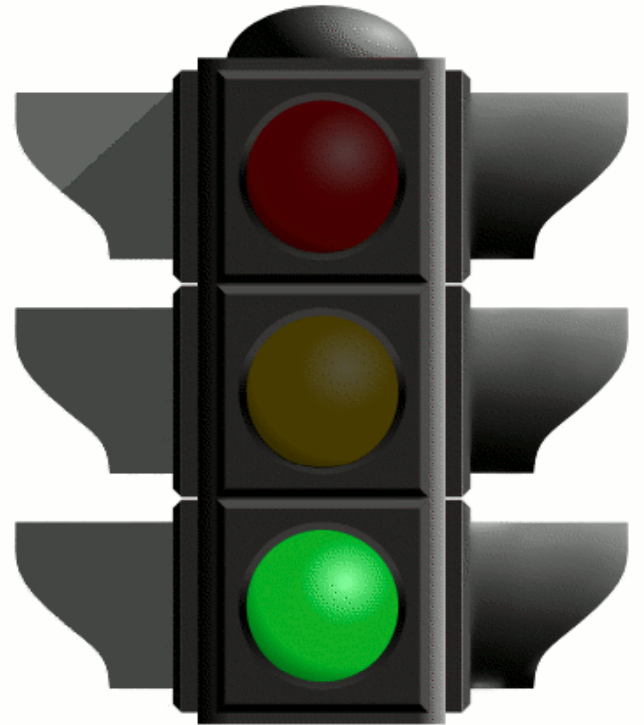
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# Indications for Frozen Plasma

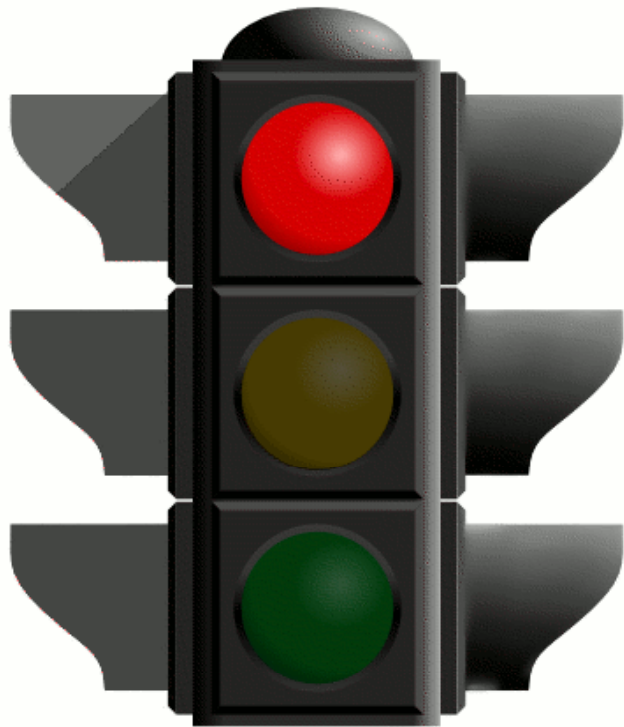
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1. Prevent bleeding in patients with abnormal coagulation results who require invasive procedures / surgery
2. Treat bleeding in patients with abnormal coagulation results
3. Thrombotic Thrombocytopenic Purpura



# Indications for Frozen Plasma

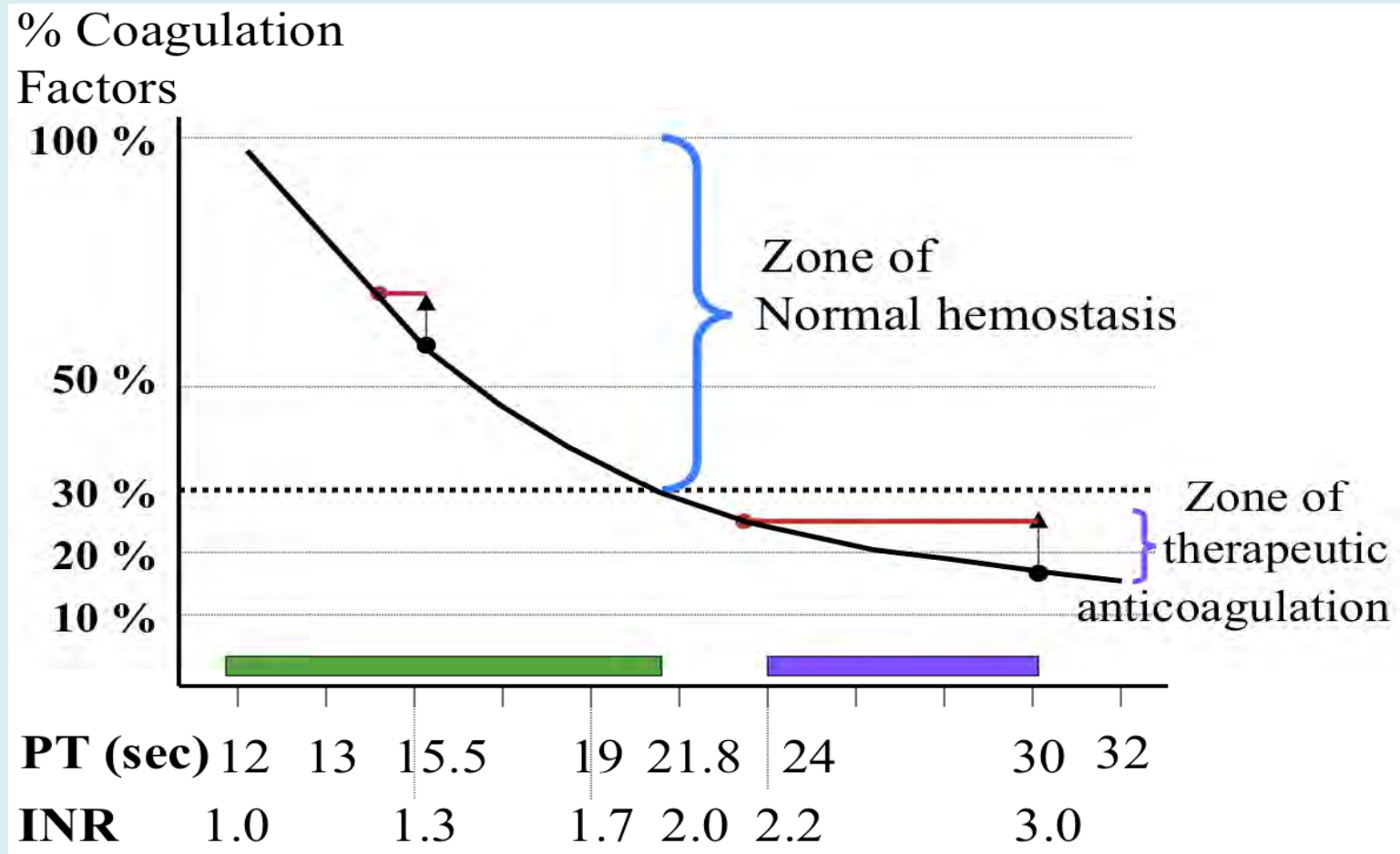
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1. What is an abnormal coagulation test result requiring treatment?
2. How long before procedure / surgery should Frozen Plasma be given?
3. Are there other options besides Frozen Plasma?



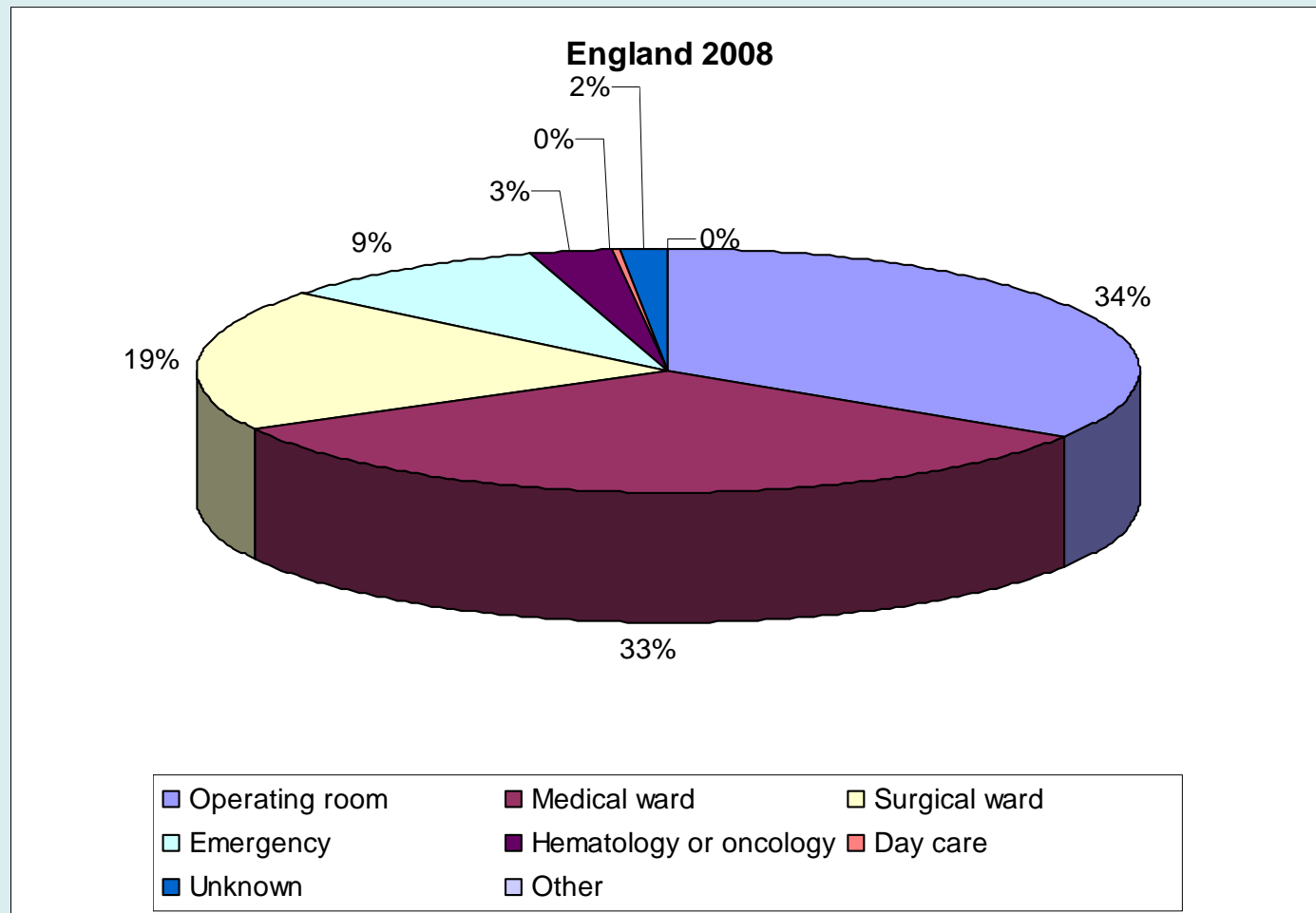
# INR and coagulation factor levels



Courtesy of Sunny Dzik (Transfusion Therapy: Clinical principles and practice. )



# FP Use in the United Kingdom



Stanworth Transfusion. 2011;51:62-70





# FP use in the United Kingdom

**TABLE 5. Changes in values for INR after transfusion of FFP in adult patients**

Adults before transfusion	Number of adult patients	Median change	Median FFP (mL/kg)
All adults	2543	-0.2	11.4, n = 1219
INR ≤ 1.5	985	0.0	10.9, n = 541
INR 1.6-1.7	344	-0.2	10.9, n = 169
INR 1.8-1.9	237	-0.3	12.1, n = 104
INR 2.0-2.1	161	-0.4	11.4, n = 81
INR 2.2-2.5	225	-0.6	11.6, n = 98
INR 2.6-2.9	113	-0.9	12.3, n = 53
INR 3.0-4.9	272	-1.8	11.5, n = 98
INR ≥ 5.0	206	-5.0	10.5, n = 75

20%

**TABLE 3. The main reasons for giving FFP in adults**

Reason for initial FFP transfusion	n = 4635
Bleeding	2503 (54)
Before (n = 1069) or during (n = 360) invasive procedure or surgery, with abnormal coagulation	1429 (31)
Abnormal coagulation with no bleeding	575 (12)
Not known	128 (3)

43%

Stanworth Transfusion.  
2011;51:62-70



# ASH Choosing Wisely campaign

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## Recommendation 4

Do not administer plasma or prothrombin complex concentrates for nonemergent reversal of Vitamin K antagonists (ie outside the setting of major bleeding, intracranial hemorrhage, or anticipated emergent surgery)



# The 6 year Journey in Ontario...

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2008 Provincial Plasma Steering Committee established

2008 First Frozen Plasma Audit

2009 Provincial Plasma Audit Report

2009 Ontario Recommendations for the Use of FP circulated

2009 Guidelines for the Use of PCCs – NAC (2011)

2010 Frozen Plasma Toolkit launched by ORBCoN

2013 Second Frozen Plasma and PCC audit

2014 Preliminary results of second audit



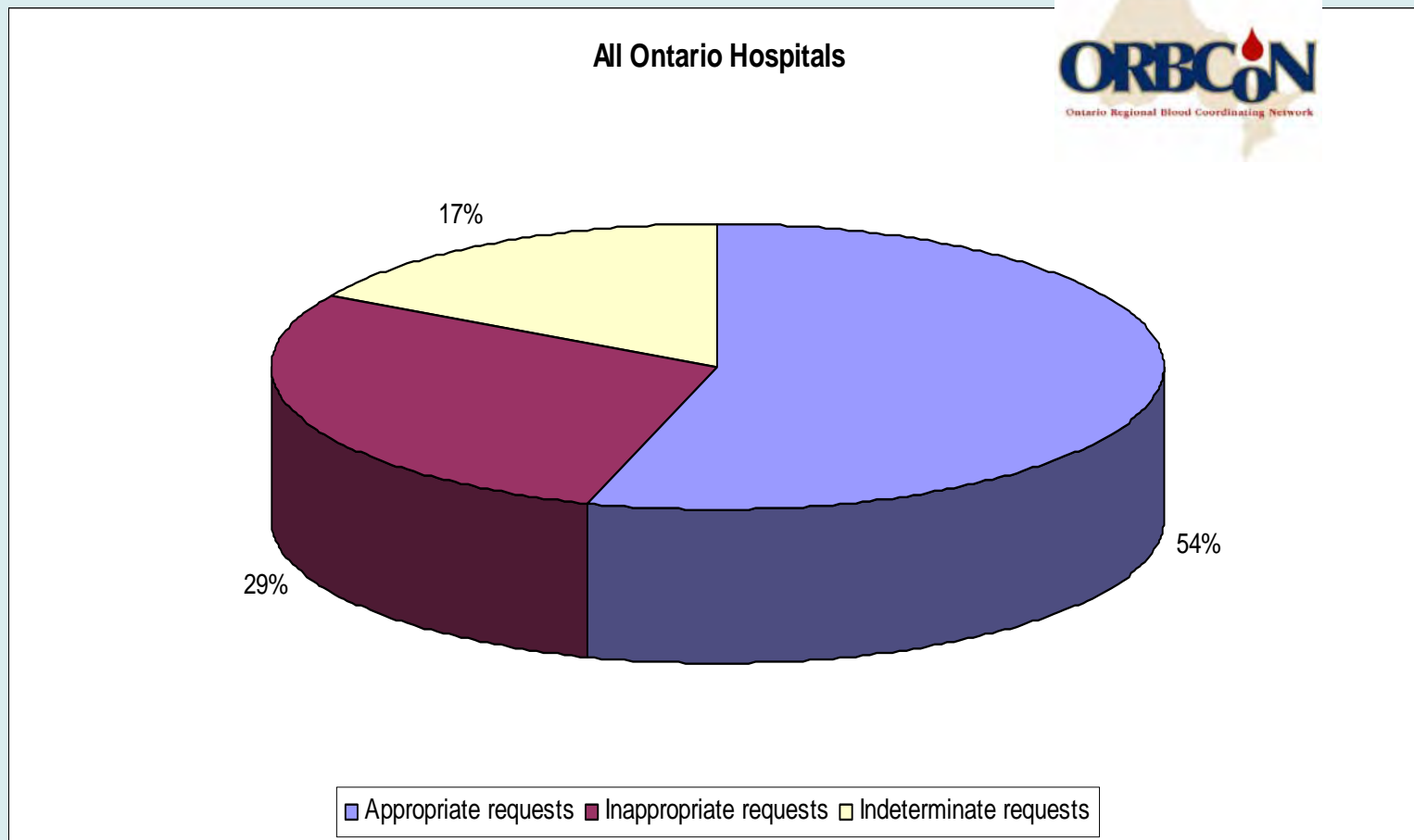
# Frozen Plasma Audits

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- **2008 baseline audit** – prospective 5 day review of transfusion episodes with associated clinical indications and laboratory data during a one month period across the province of Ontario
  - 76 hospitals participated, 88% of FP consumed
- **2013 audit** repeated– similar process but inclusive of PCCs, 5 days during a one month period, electronic data entry



# Appropriateness of Frozen Plasma Use in Ontario in 2008



**Only 29%** met the criteria for appropriate indication and the recommended dose range



# Most Common Inappropriate Use FP 2008 Audit

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- Treatment for mild abnormalities of coagulation tests not associated with increased risk of bleeding
- Correction of abnormal coagulation tests in absence of bleeding or emergency surgery
- Elective reversal of warfarin
- Emergency reversal of warfarin when PCCs are available
- Reversal of anticoagulants other than warfarin



## The Ontario Clinical Practice Recommendations for the Use of Frozen Plasma (FP)

### Situations in which the transfusion of FP is reasonable:

Clinical Indication	Reason
Bleeding	Liver disease or DIC with INR above 1.5
	Massive transfusion (expect more than 10 RBC units transfused in 24 hours) with INR above 1.5 (or rapidity of bleeding does not allow for MD to wait for results)
	Reversal of warfarin or vitamin K deficiency only where intravenous vitamin K would not suffice <b>and</b> prothrombin complex concentrate (Octaplex®) is unavailable
	Inherited or acquired single factor deficiencies where specific factor concentrate is unavailable
Emergency surgery or major procedure (within 6 hours)	Reversal of warfarin or vitamin K deficiency only where intravenous vitamin K would not suffice <b>and</b> prothrombin complex concentrate (Octaplex®) is unavailable
Surgery or major procedure	Liver disease or DIC with INR above 1.5
	Inherited or acquired single factor deficiencies where specific factor concentrate is unavailable
Plasma exchange	Thrombotic thrombocytopenic purpura (TTP)

### Situations in which transfusion of FP is NOT useful:

- INR 1.5 or less (including major or minor procedure/surgery)\*
- Use of 1:1 (FP:RBC) replacement when patient is unlikely to require massive transfusion
- Coagulopathy in the absence of bleeding or need for emergency surgery
- Elective reversal of warfarin where time allows for warfarin cessation and/or use of vitamin K
- Reversal of anticoagulants other than warfarin (eg: heparin/LMWH, rivaroxaban)
- Volume expansion or "nutrition support"

# Frozen Plasma Toolkit

*Prepared by*



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## National Advisory Committee on Blood and Blood Products Recommendations for Use of Prothrombin Complex Concentrates

### **INDICATIONS:**

#### Recommended in:

- A. Reversal of warfarin therapy or vitamin K deficiency in patients exhibiting major bleeding manifestations.**
  
- B. Reversal of warfarin therapy or vitamin K deficiency in patients requiring urgent (< 6 hours) surgical procedures.**

#### Contraindicated in:

- A. Patients with a history of Heparin Induced Thrombocytopenia**

#### Not recommended\* for:

- A. Elective reversal of oral anticoagulant therapy pre - invasive procedure.**
  
- B. Treatment of elevated INRs without bleeding or need for surgical intervention.**
  - For management of vitamin K antagonist overdose with elevated INR but without bleeding, please refer to the ACCP 2008 recommendations.
  
- C. Massive transfusion**
  
- D. Coagulopathy associated with Liver dysfunction**
  
- E. Patients with recent history of thrombosis, myocardial infarction or Disseminated Intravascular Coagulation (DIC)**



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## TRANSFUSION PRACTICE

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### **Utilization of frozen plasma in Ontario: a provincewide audit reveals a high rate of inappropriate transfusions**

*Alan Timmouth, Troy Thompson, Donald M. Arnold, Jeannie L. Callum, Kate Gagliardi, Deborah Lauzon, Wendy Owens, and Peter Pinkerton*

Transfusion, Vol 53, October 2013



# FP/PCC Audit 2013

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- All Ontario hospitals invited to participate
- All orders of FP and/or PCC during any 5 day period (Nov 18/13 - Dec 13/13)

## Data collected

- Hospital site (coded)
- Patient care area
- Date of transfusion
- Patient identification by study code number
- Patient age (YOB)
- Gender
- Indication for FP/PCC transfusion including baseline coagulation results
- Number of units/vials ordered and transfused
- Ordering physician specialty



# FP/PCC Audit Tool

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- Web-based data entry tool used for data collection
- Tool creates auto-generated site reports
- Can also export all audit data to Excel for data manipulation
- All Ontario hospitals have access to the web-based tool



# A starting point...

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YES

Does your facility have institutional guidelines for the use of Frozen Plasma? 31/51 (61%)

If yes, are your guidelines based on the Ontario Recommendations for the Use of Frozen Plasma following the last audit in 2008? 30/31 (97%)

Does your facility stock prothrombin complex Concentrates (PCC)? 51/51(100%)

Does your facility have guidelines for the use of PCC? 51/51(100%)



# Preliminary Data 2013 Audit

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- Highlights of audit
  - 51 sites participated in the FP/PCC provincial audit as compared to 76 sites in the previous audit
  - Participating sites account for 60% of plasma utilization in the province (FY 2013)
  - 34 sites participated in both audits
  - 331 orders of FP resulting in 926 units of FP being transfused
  - 113 orders for PCCs resulting in 402 vials of PCCs being transfused

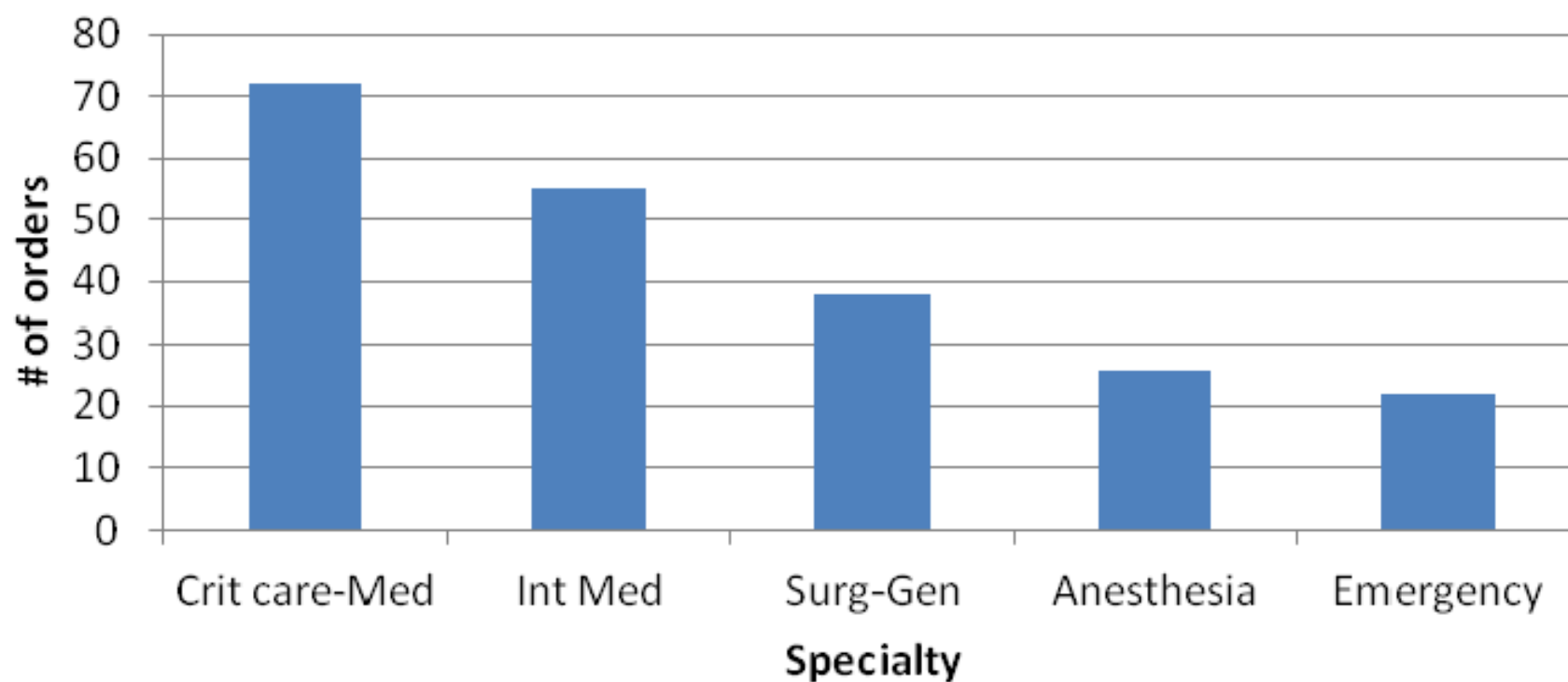


# 2008 vs 2013 Audit results

	2008	2013
# of FP requests	573	331
# of FP units ordered	2012	973
# of FP units transfused	1909	926
# of PCC requests	N/A	113
# of PCC transfused	N/A	402



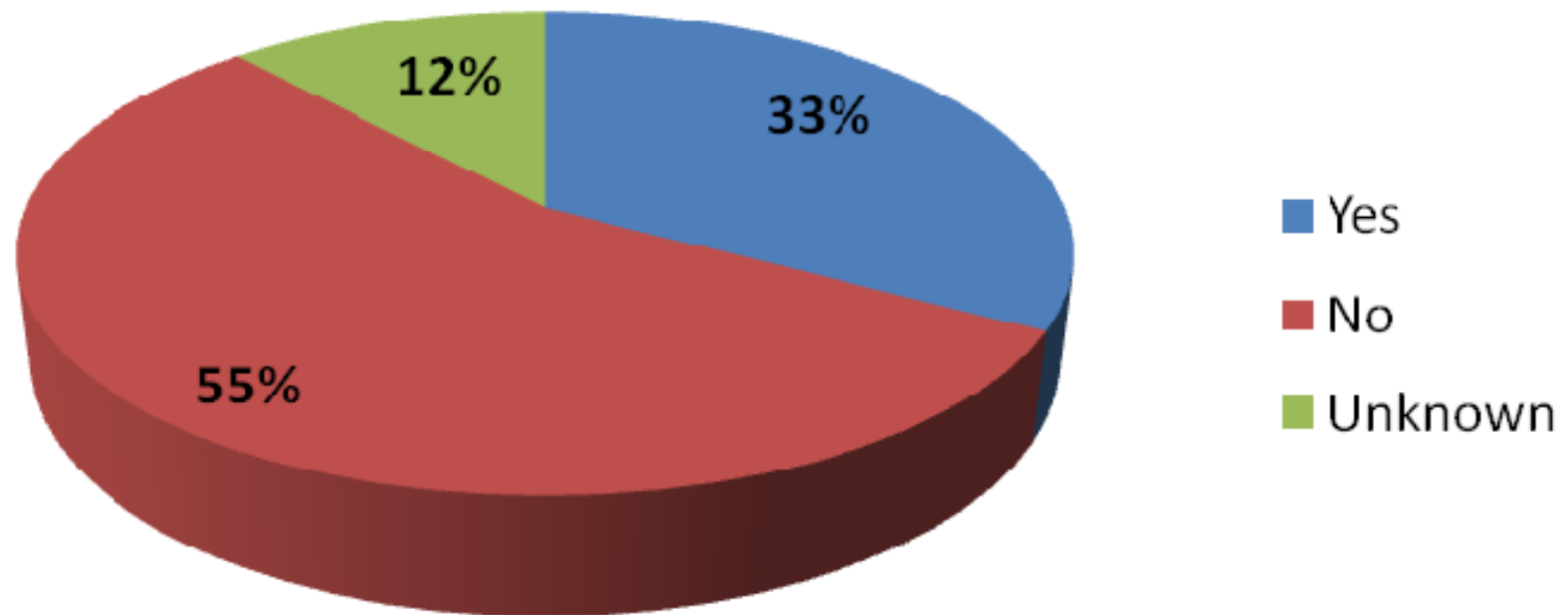
## FP orders- Top 5 ordering specialities n=331





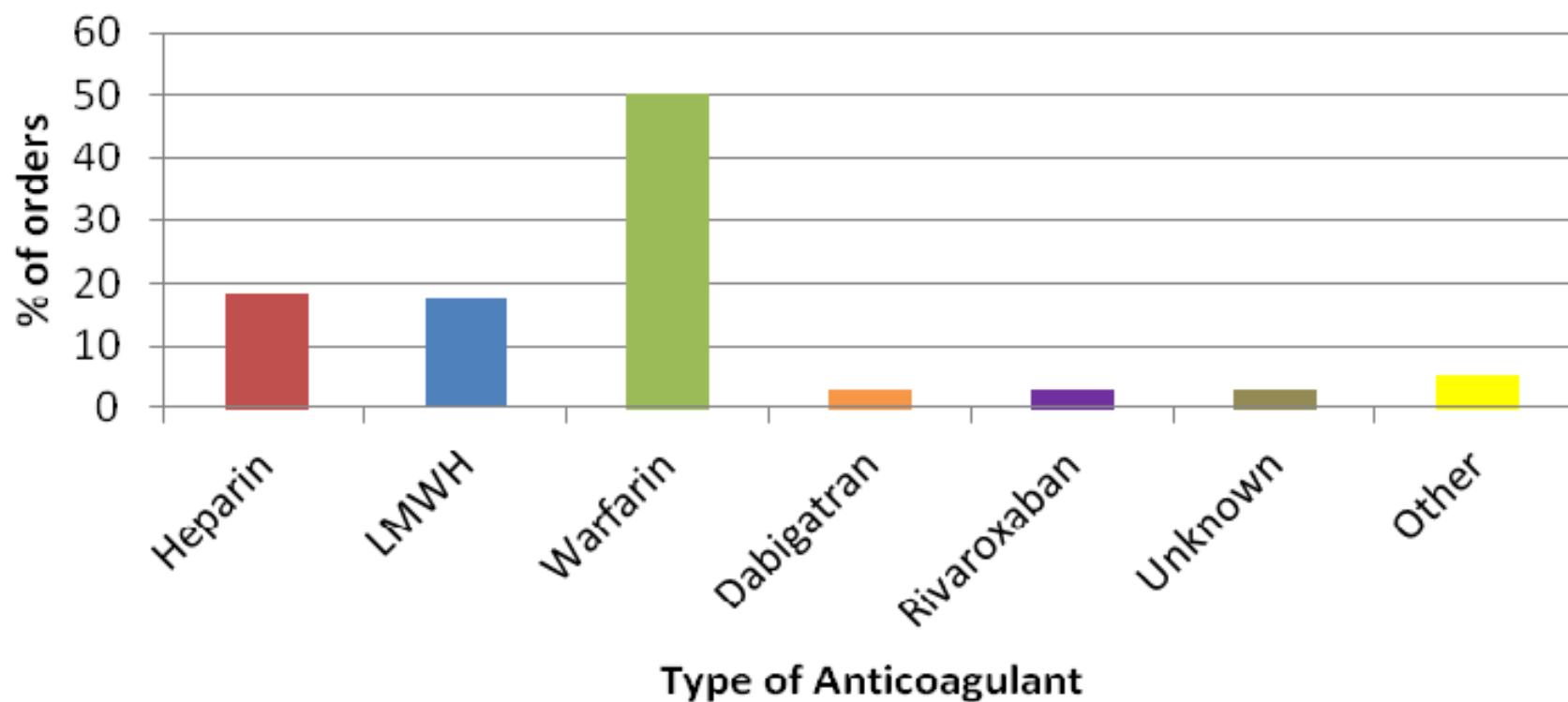
## FP orders- % on anticoagulants

(n=331 orders)



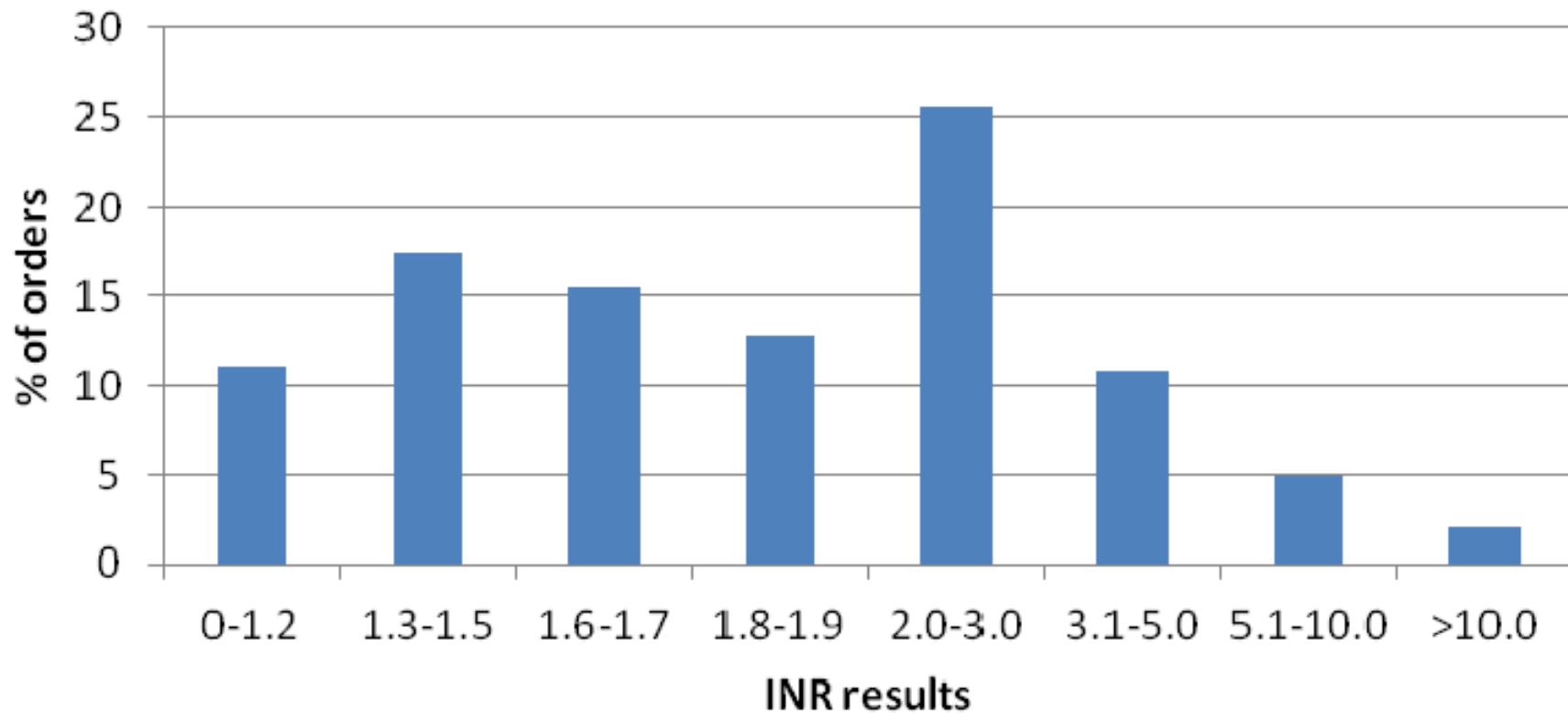
## FP orders- type of anticoagulant (%)

(n=109)



## FP orders- Pre txn INR results (%)

n=305

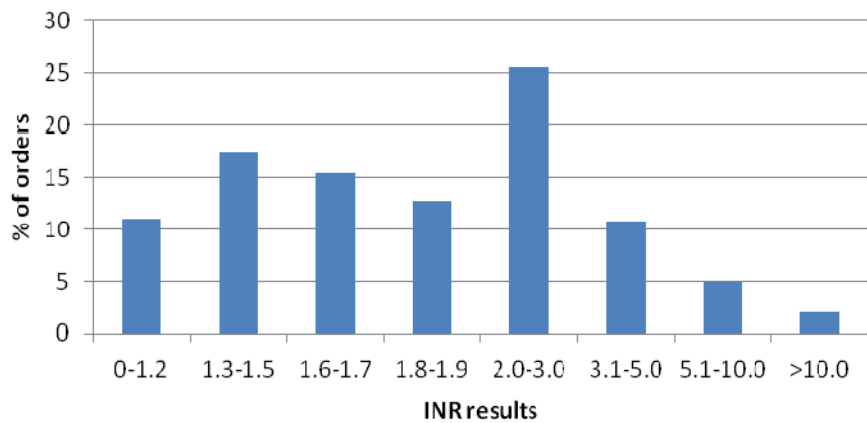


305/331 (92%) of FP orders had pre txn INR results



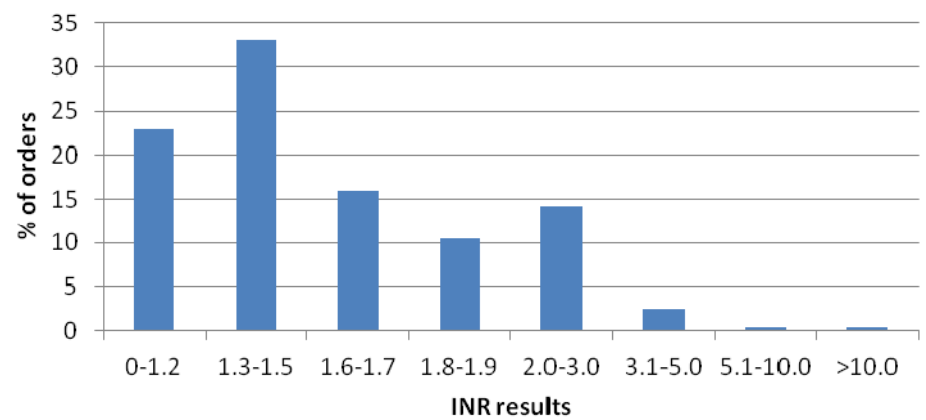
### FP orders- Pre txn INR results (%)

n=305



### FP orders- Post txn INR results

n=239



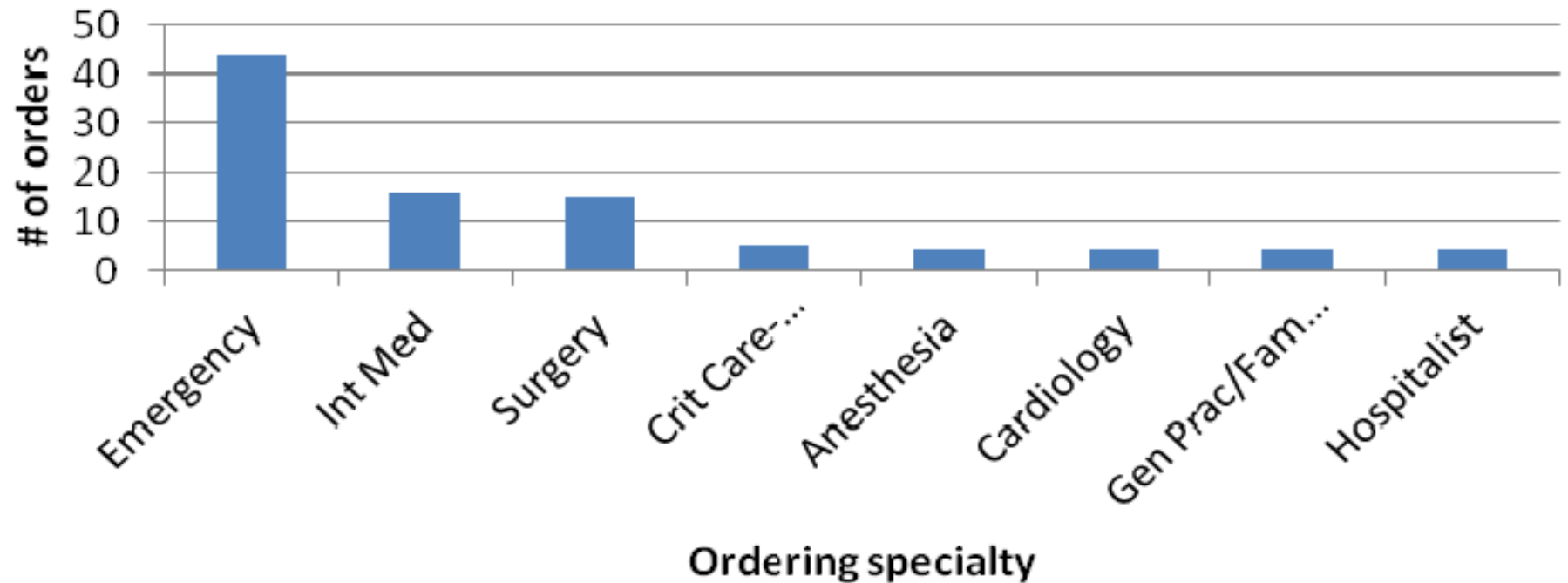
305/331 (92%) of FP orders had pre-txn INR results

239/331 (72%) of FP orders had post-txn INR results



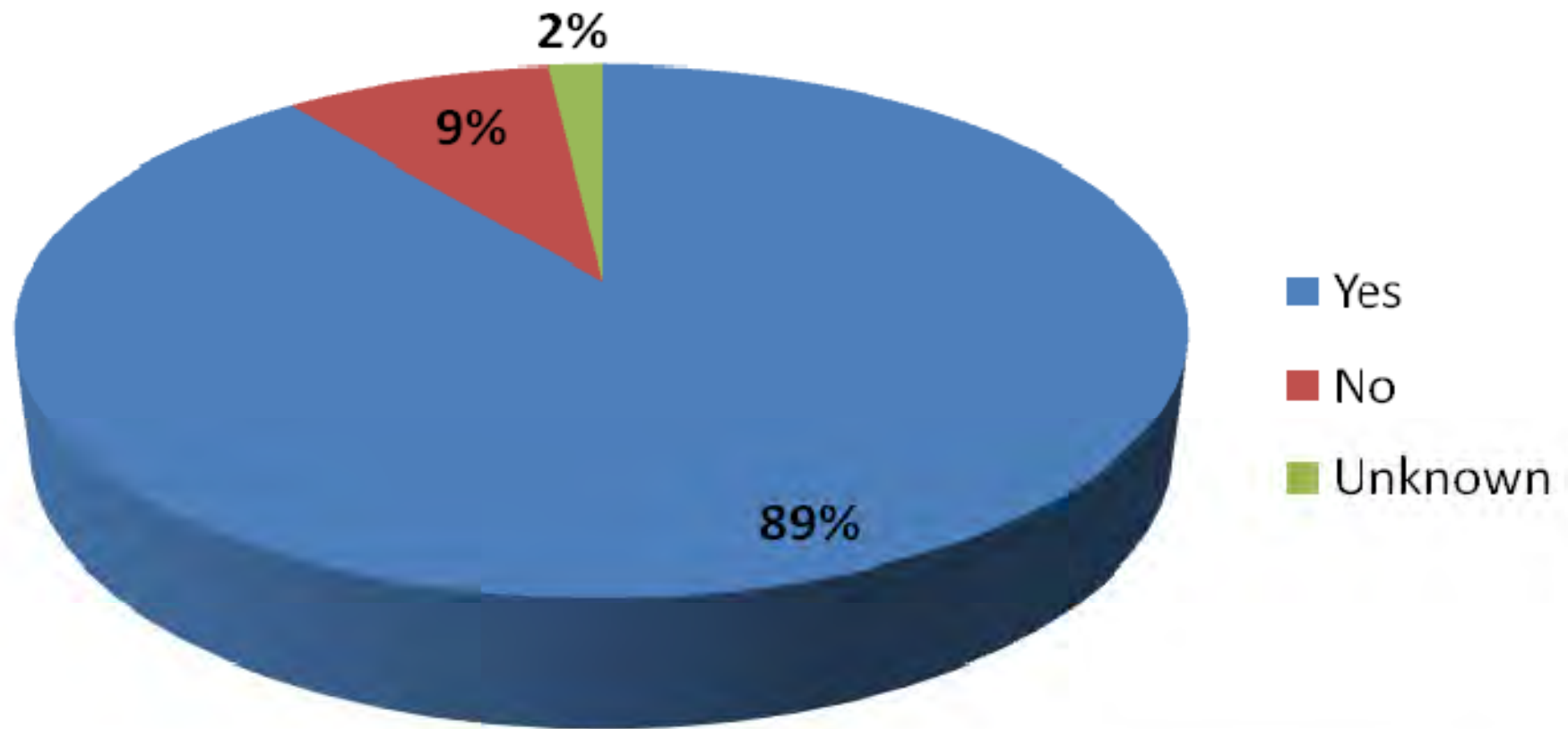
# PCC orders- Top ordering specialties

n=113

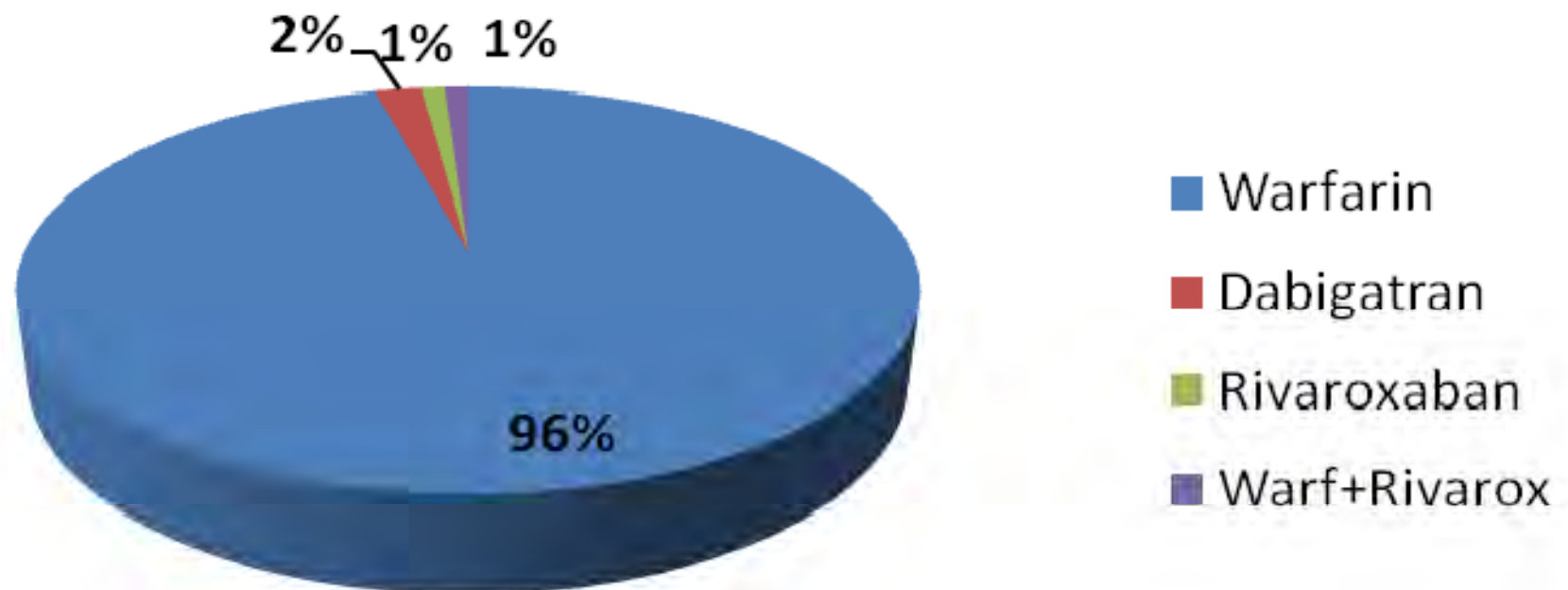


## PCC orders- on anticoagulants

(n=113 orders)

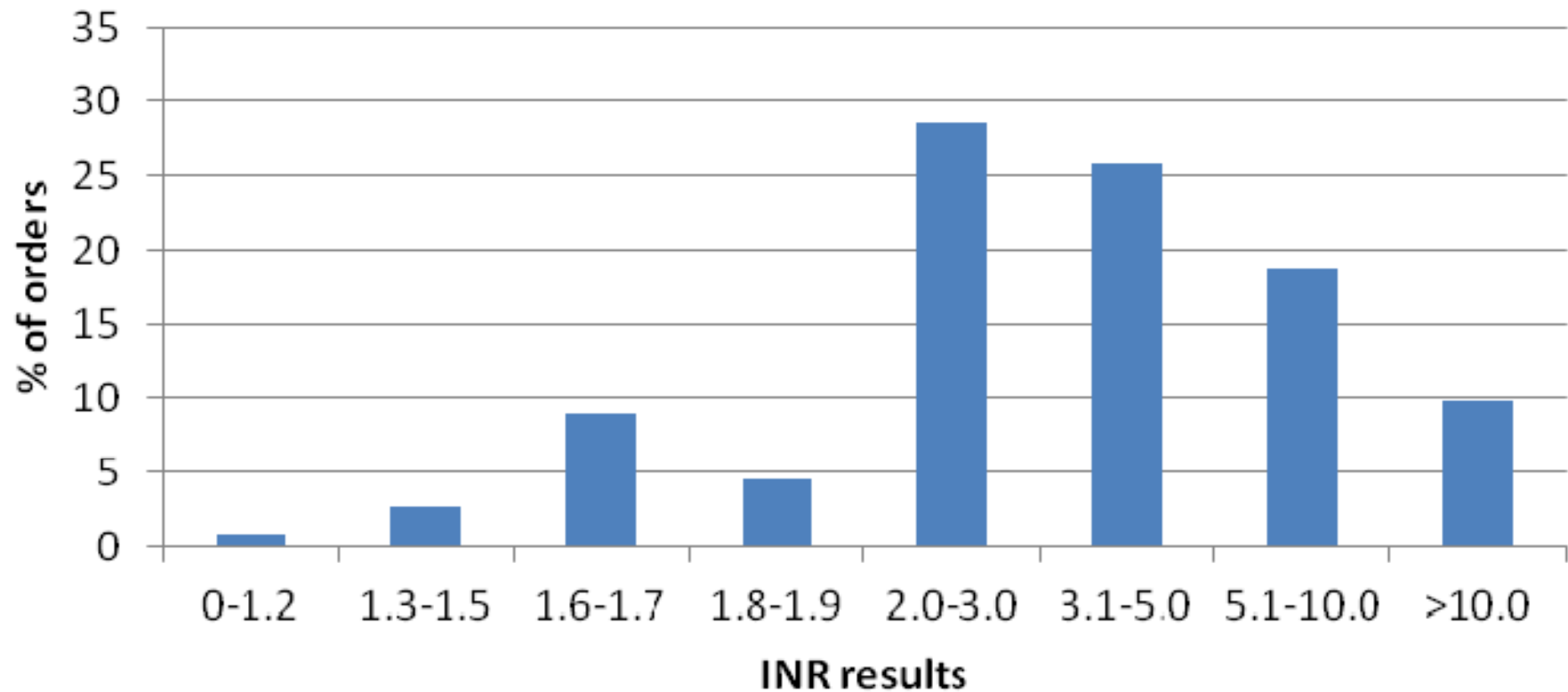


## PCC orders- Type of Anticoagulant (n=113 orders)



# PCC orders- Pre txn INR results

(n=112)



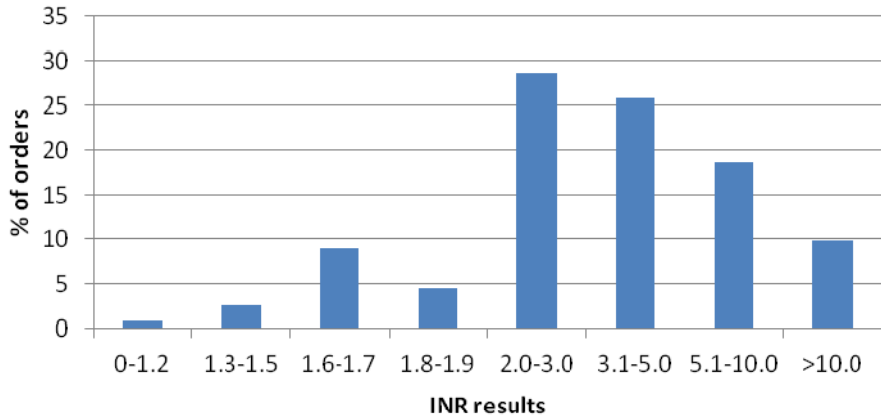
112/113 (99%) PCC orders had pre txn INR results





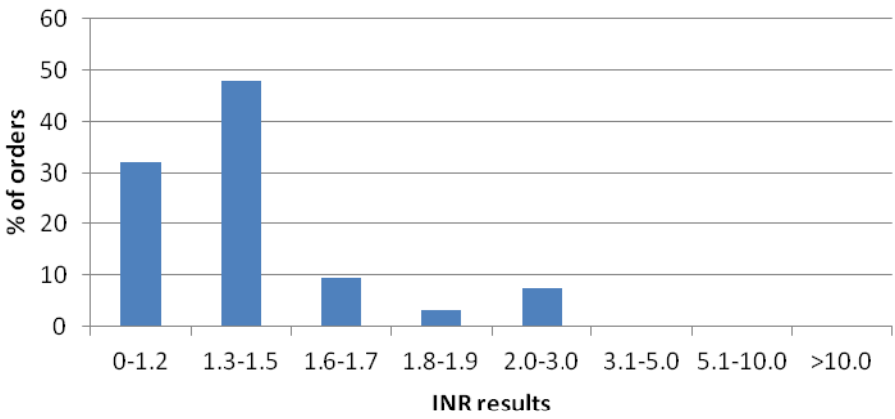
### PCC orders- Pre txn INR results

(n=112)



### PCC orders- Post INR results

n=96

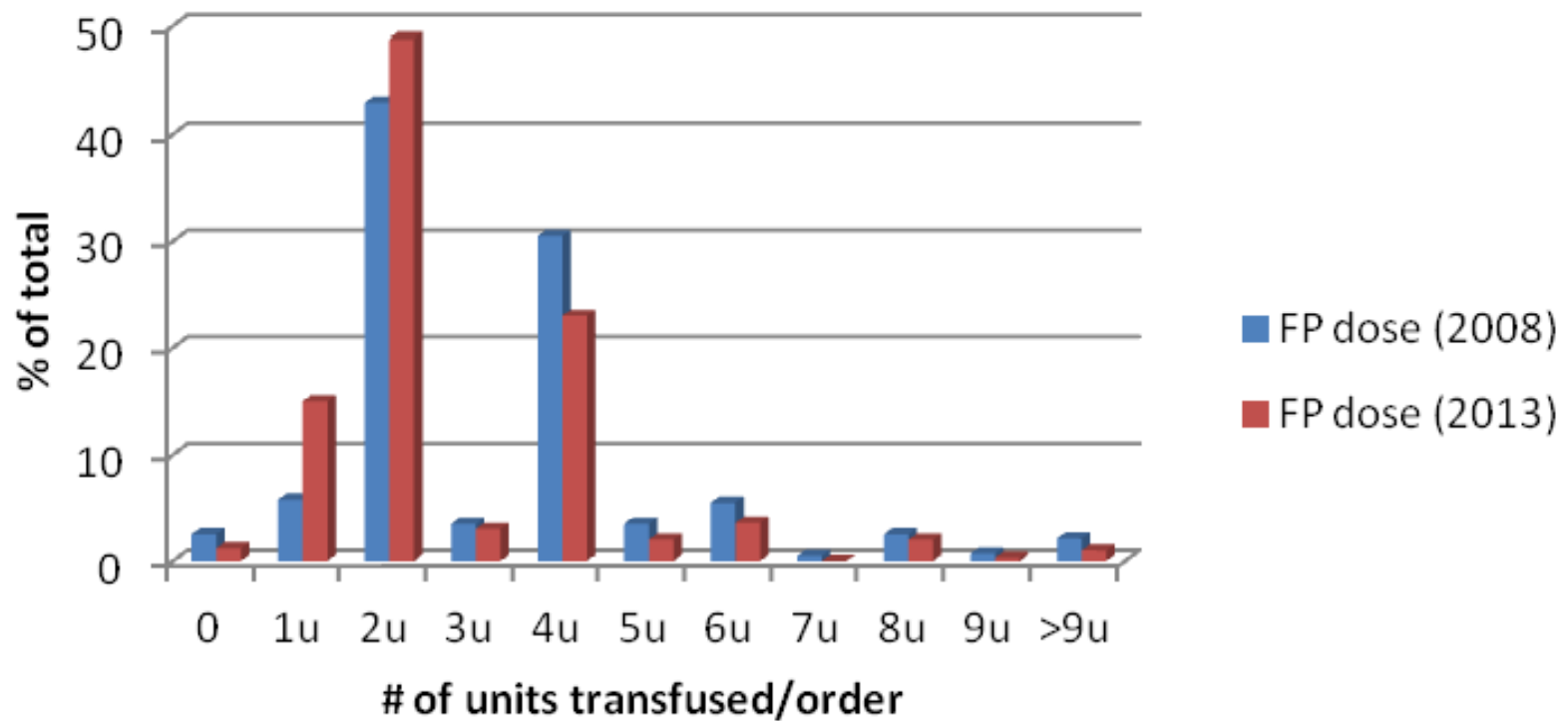


**112/113 (99%) of PCC orders had pre-INR test results**

**96/113 (85%) of PCC orders had post-INR test results**



### Distribution of FP dose transfused 2008 vs 2013 audit (% of total transfusions)



# Adverse Transfusion Reactions

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??? Only 1 adverse event reported – Allergic: hives



# What's next?

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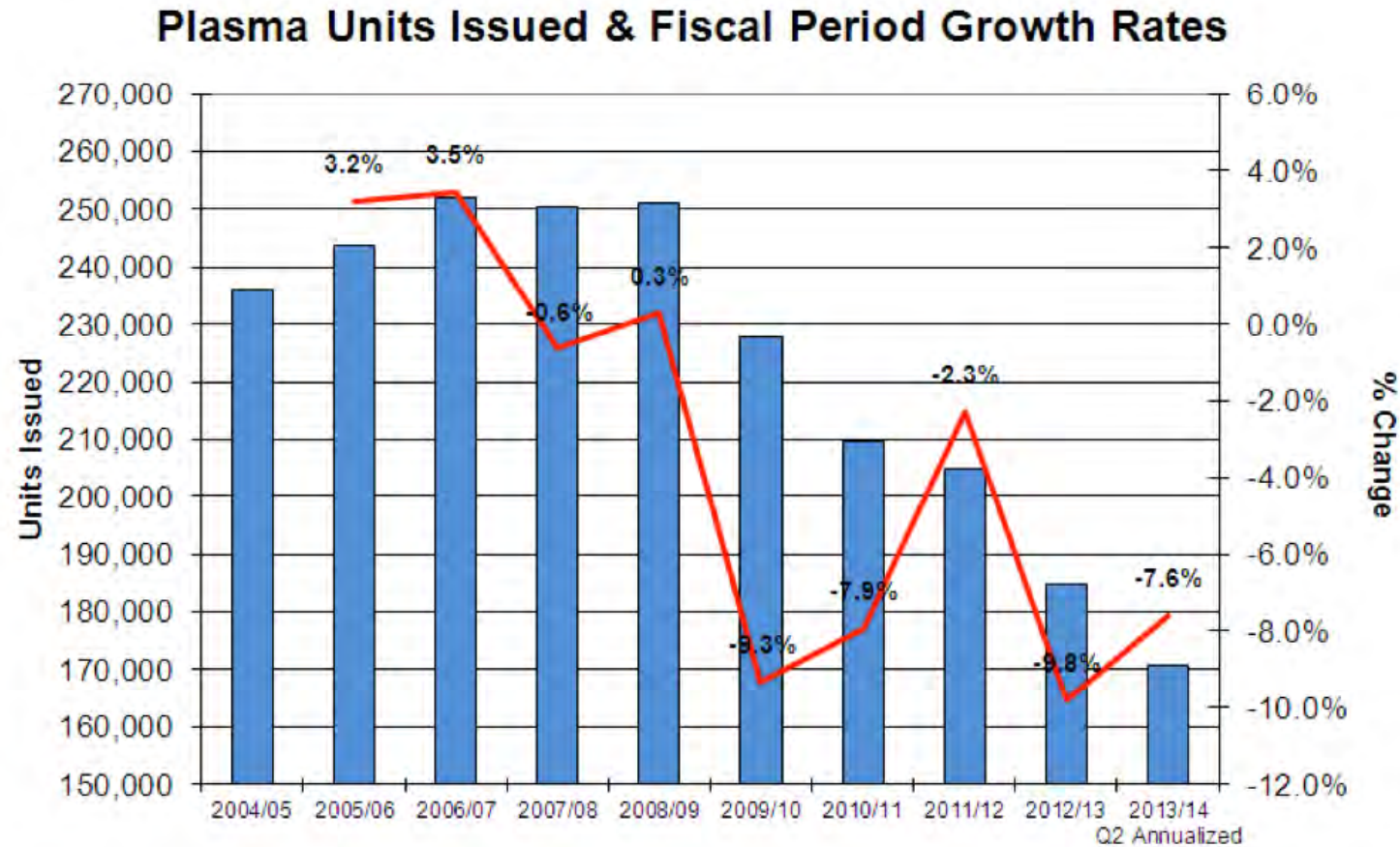
Did the provincial audit, the Ontario recommendations and ORBCoN's toolkit have an impact on ordering practices?

Why are we still seeing the same problems?

How can we use the information from these audit experiences to improve ordering practices?



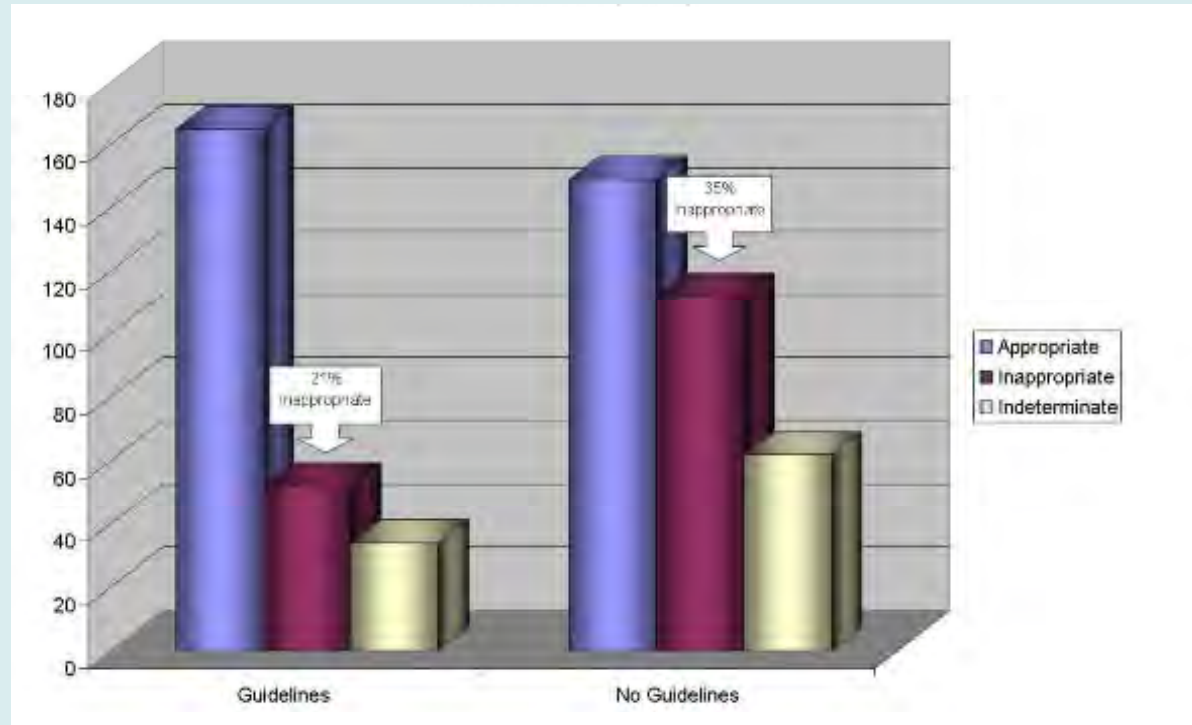
# FP Use in Canada (excluding Quebec)



Courtesy R. Trifulnov. Canadian Blood Services



# Are Guidelines Effective? 2008 Audit



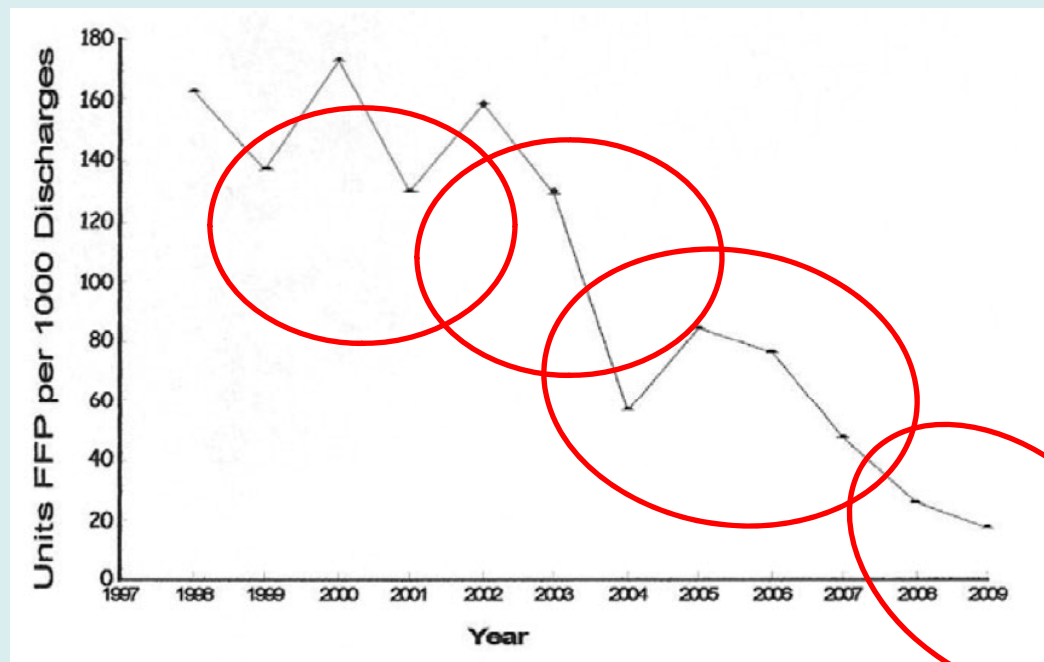
Orders	Guidelines	No Guidelines	P value
Appropriate	165 (65.7%)	149 (46.3%)	p<0.0001
Inappropriate	52 (20.7%)	112 (34.8%)	p<0.0003
Indeterminate	34 (13.5%)	61 (18.9%)	0.08

# Reduction in FP transfusion after enforcement of guideline

## Tertiary care U.S. Hospital

- 2001 new guidelines
- 2001-2003 education
- 2003 – 2006 FP requests screened by technologist
- 2006+ MD review

Tavares et al. Transfusion  
2011; 51: 754.



# Preliminary Conclusions

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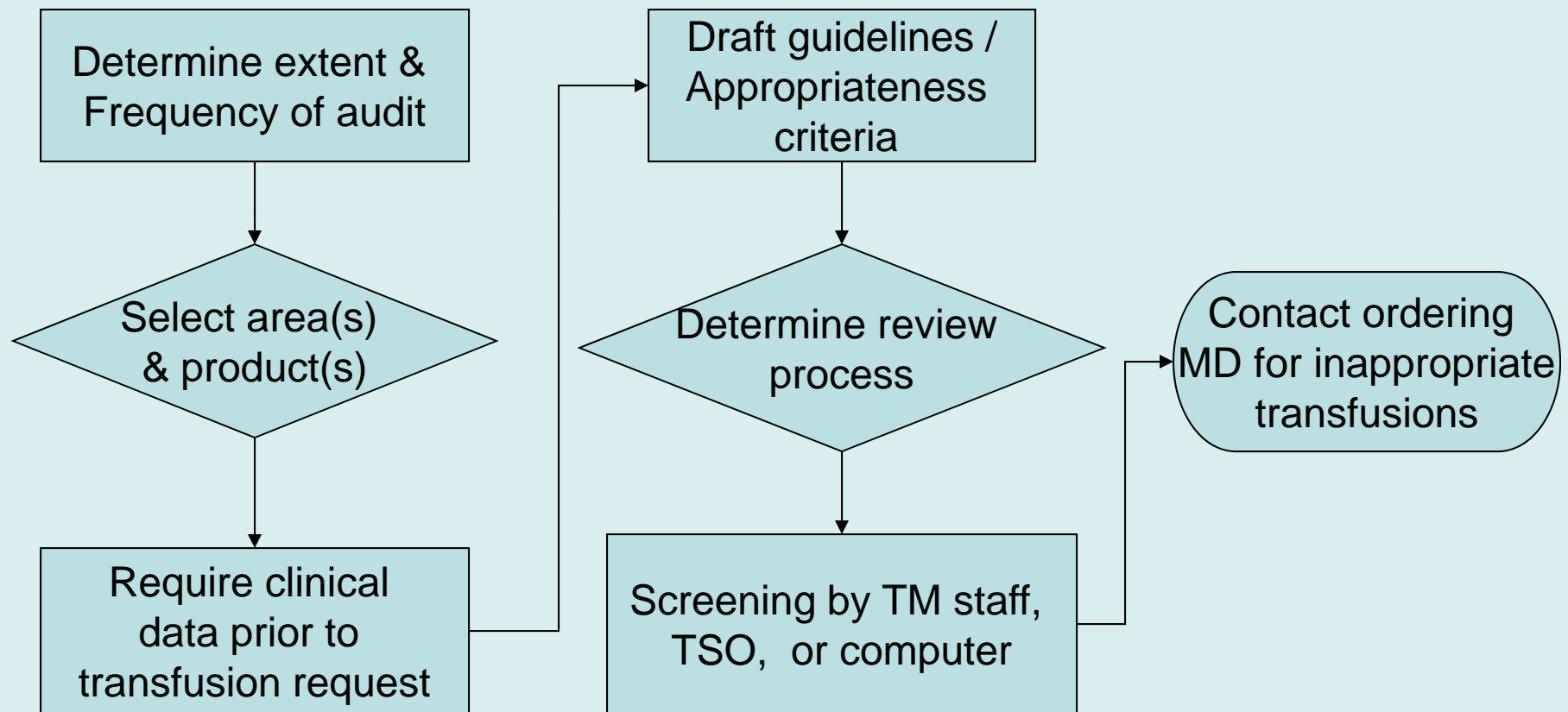


- Continued high rate of inappropriate use of frozen plasma both for indications and dose
- Upfront requirement for guidelines and screening may lead to more appropriate use of products
- Detailed review of audit results, adjudication of FP and PCC requests and transfusion ongoing
- Need to consider next steps to reduce inappropriate use





# Implementing a prospective audit



# Going Forward...

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- Audits are required by Standards for transfusion medicine
- Necessary part of Transfusion Committee as part of monitoring blood utilization
  - Critical to understand utilization of blood products
  - Required to determine if areas that need improvement
  - Site specific information will be provided
- Critical that the information is used to improve transfusion practice
  - Shared with users of blood products
  - Combined with other interventions



# Acknowledgements

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Central Region

The Plasma Audit Steering Committee

Dr. Alan Tinmouth

Troy Thompson

MOH LTC

Ontario Blood Advisory Committee

