ENGELBERG CENTER for Health Care Reform at BROOKINGS

Developing Systems to Support Pharmacovigilance of Biologic Products

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Engelberg Center for Health Care Reform
The Brookings Institution
Washington, DC
November 15, 2013

Pharmacovigilance issues related to the identification of biologics/biosimilars

- Administrative claims data could misclassify drug exposures when a newly licensed biologic is administered by a healthcare provider: the provider will typically submit claims containing a HCPCS code that is not specific to the new agent.

- Newly licensed medications may be assigned a non-specific HCPCS code
  - J3490: unclassified drugs
  - J3590: unclassified biologics

- Permanent, specific HCPCS codes are assigned one to two years after a drug comes to market.

- For an agent using one of the non-specific “J” codes, the name, strength of the drug (if applicable) and the actual dosage administered must be indicated on the CMS-1500 form in Block 19 or Block 24 (listed with the procedure code).

- Block 19 data are NOT included in Medicare claims data.

Identifying Biologic Exposures for Newly Licensed Medications

	Tocilizumab	Certolizumab Pegol	Denosumab
Non Specific J code	J3490, J3590, J9999, C9399, Q4082		
Specific J code (date assigned)	J3262 (January 2011) C9264 (July 2010, institutional use only)	J0718 (January 2010) C9249 (April 2009, institutional use only)	J0897 (January 2012) C9272 (October 2010, institutional use only)
Associated diagnosis code sought on claim*	714 (rheumatoid arthritis)	714 (rheumatoid arthritis), 555 (Crohn's disease), 556 (ulcerative colitis), 6960 (psoriatic arthritis), 6961 (psoriasis), 7200 (ankylosing spondylitis)	733 (disorders of bone and cartilage, including osteoporosis)
Unit price** and effective date	3.519/Jan 1, 2010 3.477/Oct 1, 2010	3.417/Jan 1, 2009 3.515/Apr 1, 2009 3.584/Jul 1, 2009 3.800/Oct 1, 2009	14.575/Oct 1, 2010
Unit Count (i.e. dose) Typical Unique from other drugs Possible Unit Count	 200,400,600,800 Combination of 200s and 80s(not multiple of 100s) 1, 2, 3, 4…	 200,400 N/A 1,2	 60 60 1
Infusion code***	96413, 96415	none	none
Injection code***		96372, 96374, 96375	96372, 96374, 96375, 96401
Expected dosing frequency	Every 4 weeks	Every 4 weeks	Every 6 months

Curtis JR, Xie F, et al. PDS 2013

Future Challenges and Potential Solutions

- **Impact on patients, providers, and reimbursement program**
  - Challenge the billing and reimbursement system
  - Physicians send the patients to hospital infusion center
  - Patients purchase medications through Part D coverage

- **Potential solutions to avoid misclassification on newly approved biologics**
  - Report NDC codes submitted in Block 19 in Medicare physician file along with J codes
  - Assign specific J codes immediately when infusion drugs approved

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Blood Safety Continuous Active Surveillance Network

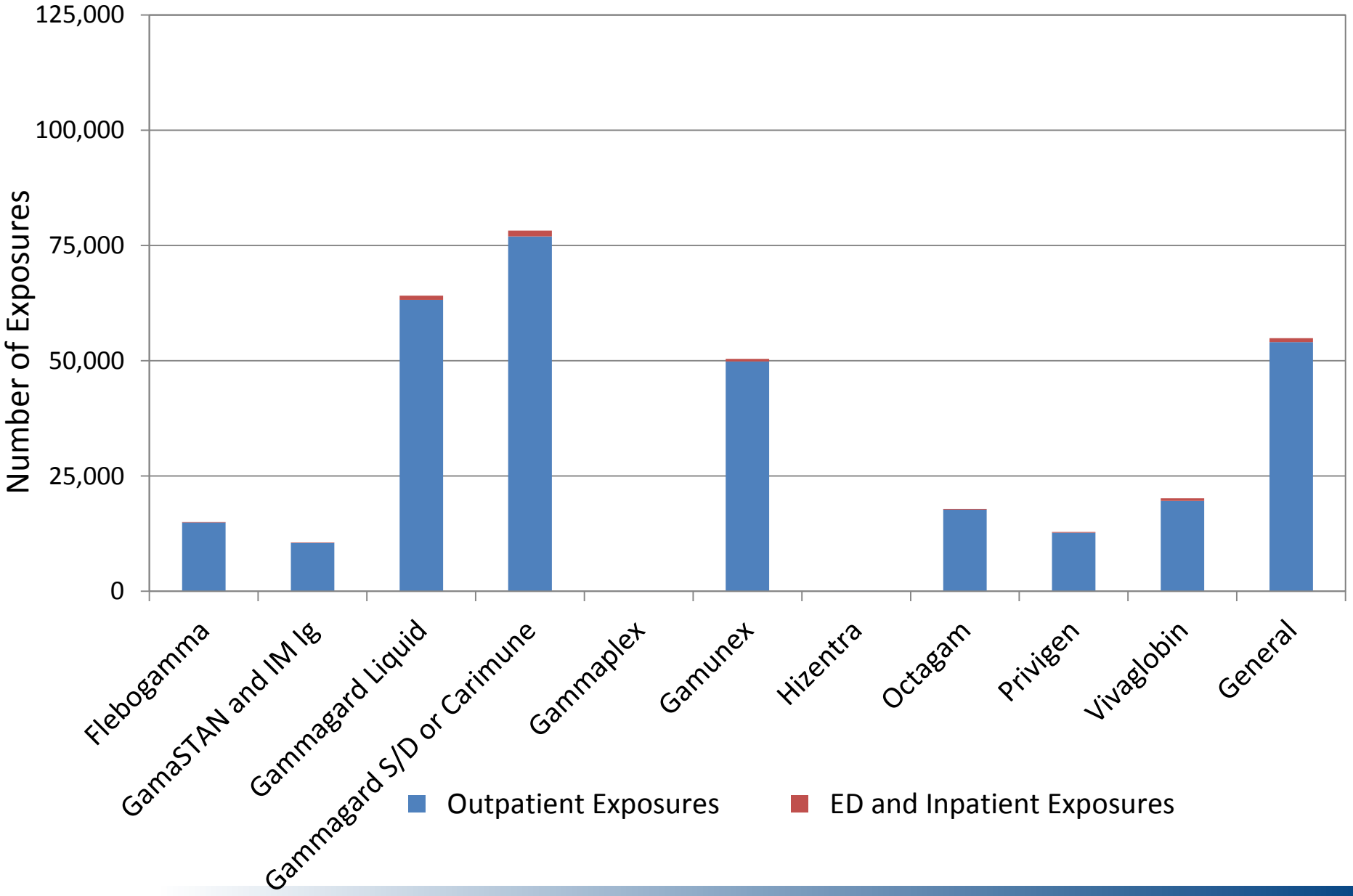
Meghan Baker, MD, ScD
Harvard University
Harvard Pilgrim Health Care Institute

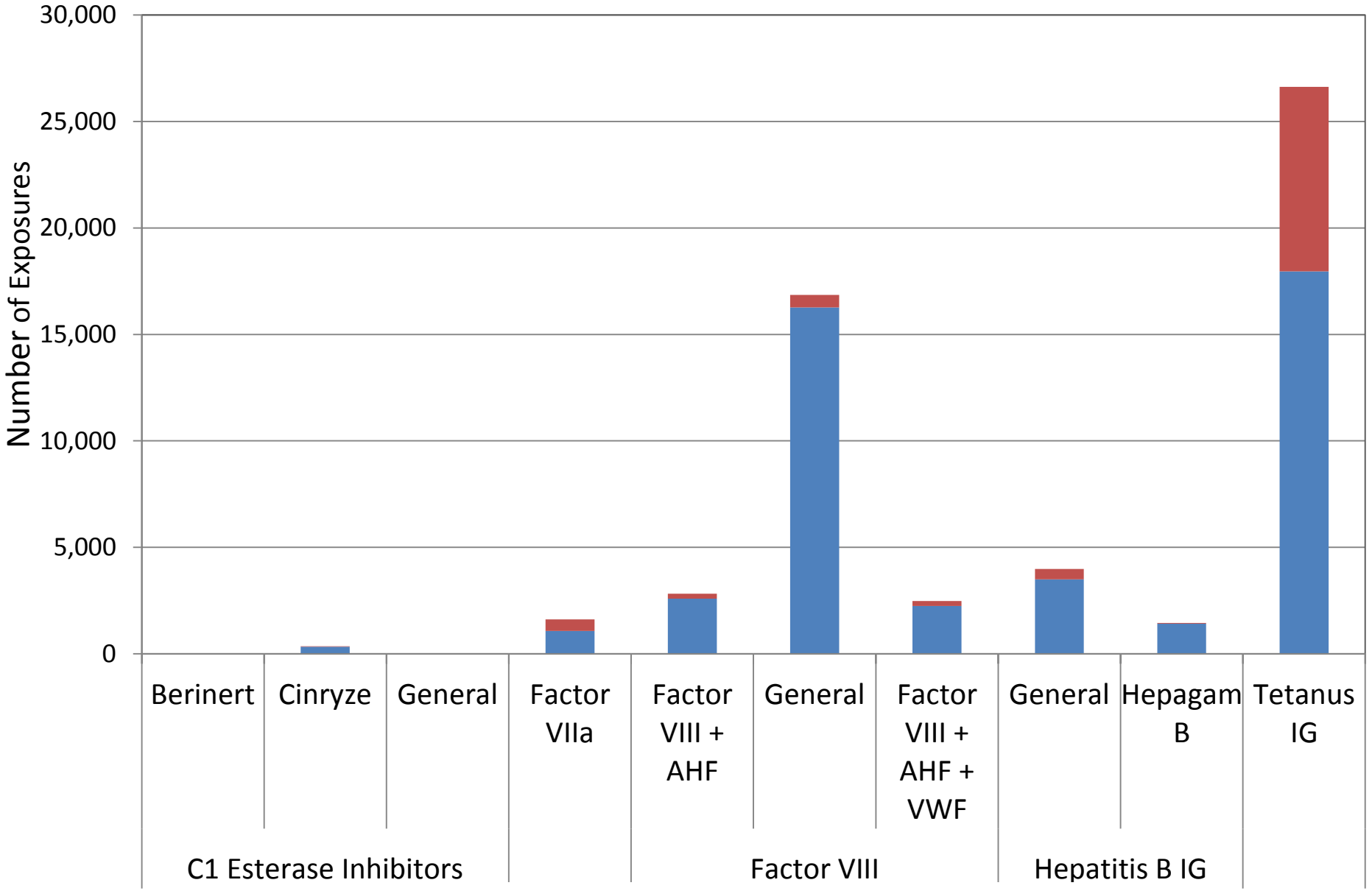
November 15, 2013

Exposure Ascertainment

Location	Route of Administration	Health Plans
Outpatient	Oral	
	Injection	
	IV infusion	
Inpatient	Oral	
	Injection	
	IV infusion	

Courtesy of Lesley Curtis


125,000
100,000
75,000
50,000
25,000
0
Number of Exposures
Flebogamma
GamaSTAN and IM Ig
Gammagard Liquid
Gammagard S/D or Carimune
Gammaplex
Gamunex
Hizentra
Octagam
Privigen
Vivaglobin
General
Outpatient Exposures
ED and Inpatient Exposures


30,000
25,000
20,000
15,000
10,000
5,000
0
Number of Exposures
Berinert
Cinryze
General
Factor VIIa
Factor VIII + AHF
General
Factor VIII + AHF + VWF
General
Hepagam B
Tetanus IG
C1 Esterase Inhibitors
Factor VIII
Hepatitis B IG
Outpatient Encounters
ED and Inpatient Encounters

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Registry Design and Implementation Considerations

QUINTILES

Clinically Meaningful Outcomes

Safety & Clinical Effectiveness

- Attribute safety and effectiveness outcomes to the correct product
- Track immunogenicity
- Comparative effectiveness – choice of comparators

Treatment Effect Heterogeneity

- Ensure collection of explanatory variables and potential confounders
- Concomitant treatments

Delayed Risks

- Evaluate long-term outcomes from chronic use and/or long latency periods
- Account for switching

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