



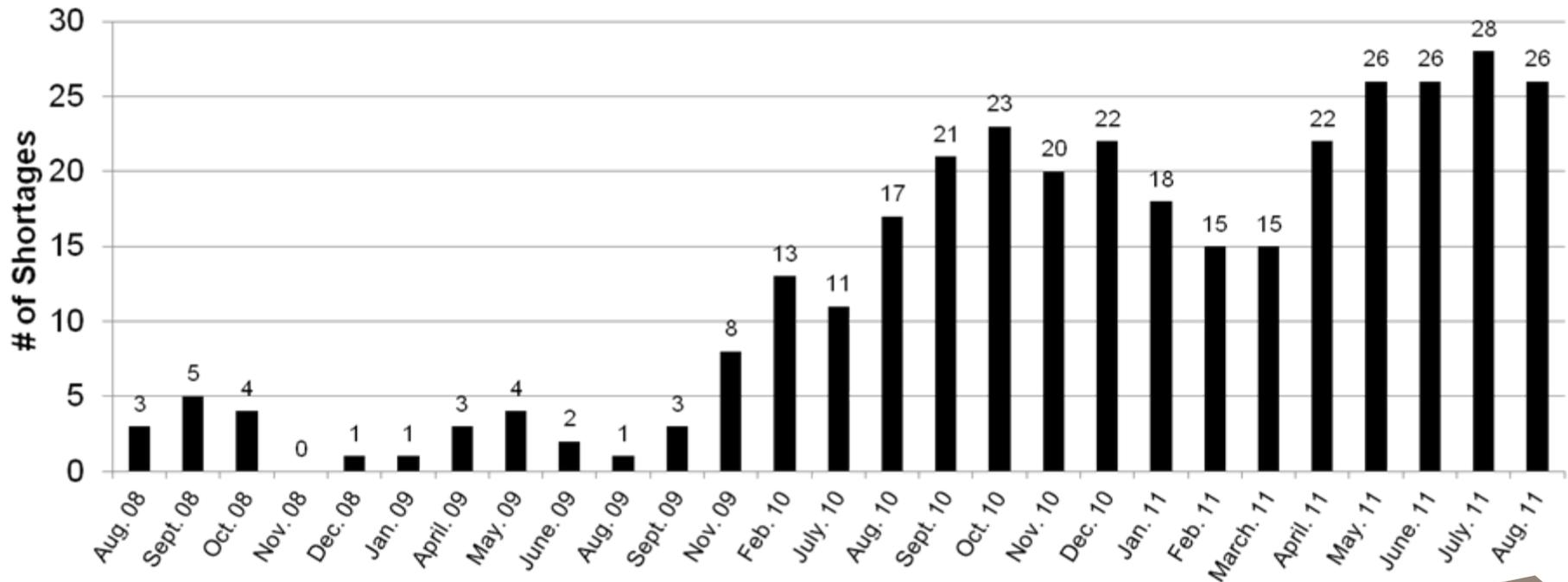
**CDER Drug Shortage Workshop**  
**Perspectives from the Point of Care -**  
**Specialty Settings**  
**St. Jude Children's Research Hospital**

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# Drug shortages at St. Jude have increased dramatically since 2009

Number of Drug Shortages at St Jude by Month  
August 2008 to August 2011





# Notable Shortages and Impact at St Jude

- Total Parenteral Nutrition (TPN)
  - Every component of TPN has been in short supply over the last year (amino acids, lipids, electrolytes, multi-vitamins)
  - Multivitamin Injection
    - Oral multivitamins substituted during IV vitamin shortage. Patient presented with neurotoxicity/thiamine deficiency due to inability to take oral multivitamins. Resulted in a hospital admission.
- Shortages may negatively affect cure rates for cancer
  - Forced to make prioritization and substitution decisions when chemotherapy shortages occur
  - Often alternative agents may not exist or there may be little or no evidence for alternative agents used
  - Therefore, long term impact of use of alternative agents on cure of children with cancer is unclear



# Drug shortages impede advancing cures for pediatric cancer

- ~85% of pediatric cancer patients enrolled on clinical trials
  - Each shortage prompts work and documentation; guidance for investigators developed by St. Jude and cooperative groups
- Cytarabine shortage
  - Standard of care and necessary to cure AML – no alternatives exist
  - Enrollment on front line AML protocols suspended
- Mechlorethamine (Nitrogen Mustard) shortage
  - All St. Jude Hodgkins Lymphoma protocols (including collaborating sites) were modified to an agent with less evidence in the disease
- Daunorubicin
  - Prioritized for ALL patients; AML substituted with Idarubicin



## Smaller Markets Pose a Challenge for the Drug Supply - Shortages Add Complexity to Curing Childhood Cancer

- 3000 pts per year with childhood Acute Lymphoblastic Leukemia (ALL) – most common childhood cancer
- Using 10 drugs, we can cure ~ 90% of pts
  - Prednisone
  - *Dexamethasone*\*
  - *Asparaginase—E.Coli*\*
  - *Asparaginase----PEG*\*
  - *Asparaginase, erwinia*\*
  - *Daunorubicin*\*
  - *Vincristine*\*
  - *Methotrexate*\*
  - *6-mercaptopurine*\*
  - Imatinib
- **\* 8 of these 10 drugs temporarily unavailable for use over last 10 years**