



CDER's Quality Management Maturity Program 2022 Public Workshop

How QMM Ratings Could Inform Drug Purchasing Organizations
Dan Kistner, PharmD, Group SVP, Vizient
May 25, 2022

vizient.[®]

Our mission

We strengthen
members' delivery
of high-value care
by aligning cost,
quality and market
performance.



Connecting the nation's top providers

We serve more than half of the health care organizations in the United States.

- Mayo Clinic
- Massachusetts General Hospital
- The Johns Hopkins Hospital
- Cedars-Sinai
- Cleveland Clinic
- Prisma Health
- New York-Presbyterian Hospital
- UCLA Medical Center

97%

Academic medical centers
in the U.S.

>50%

Acute care hospitals
in the U.S.

>20%

Ambulatory market
in the U.S.

18 of the Top 20





US News and World Report best hospitals rely on Vizient capabilities in supply chain, pharmacy, operations and quality, and strategic growth to drive success.

Our pharmacy solutions support acute and non-acute care settings

Expansive portfolio, data-driven insights

Vizient supports health systems and hospitals in transforming pharmacy from a cost center to a central point of integrated care across acute, specialty, home infusion and long-term care, through solutions that manage cost, improve quality outcomes and drive organizational performance.

Sourcing | Analytics | Advisory | Clinical insight | Networks | Specialty Pharmacy | 340B | PBM

Pharmacy program at a glance				Supporting members in the management of COVID-19 and future pharmacy spend	
 3,100 Pharmacy program participants	 \$90B+ Pharmaceutical spend	 \$3B Novaplius® private label	 12,000 Contracted products and services	3.1% July 2021 projected drug price inflation rate	100M Additional units of essential medications made available through Novaplius Enhanced Supply Program
					\$335M Inventory cost avoidance for our members

Vizient's Mission – End Drug Shortages

Members expect Vizient to play a key role

75%

of DOPs expect Vizient to help them identify best practices that they can implement to best manage drug shortages.

7 out of 10

DOPs expect Vizient to advocate about drug shortages within the industry and regulatory environment.



Overall impact of drug shortages

The increased cost of labor is real.

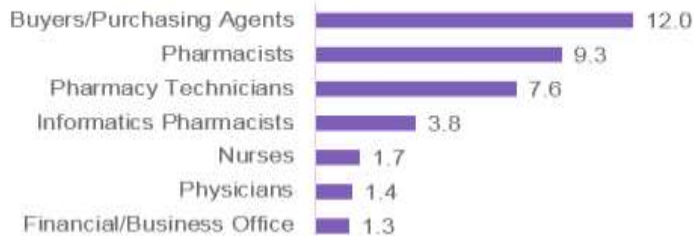
\$345 million
per year

Annual cost of labor needed to manage drug shortages

8.3 million hours

Additional hours of labor per year

Average number of hours spent weekly on managing drug shortages



Direct and indirect costs of drug shortages are high, including:

- ▶ Increases in drug budget
- ▶ Lost revenue from cancelled infusions and procedures
- ▶ Increased full-time employees for pharmacy and technicians
- ▶ Reallocation of pharmacy resources which leads to lost productivity and impact in other areas
- ▶ Documented medication errors potentially resulting in harm

Ref: U.S. hospital as defined by the American Hospital Association

<https://www.aha.org/statistics/fast-facts-us-hospitals>

Ref: Definitive Healthcare *Hospitals and IDNs database*

Ref: Vizient pharmacy program participants; data on file

Ref: Hourly pay based on U.S. labor statistics <https://www.bls.gov/>; Vizient data on file

Resiliency strategies

Providing consistent access to essential medications



Identify essential medications



Drive additional supply into the market

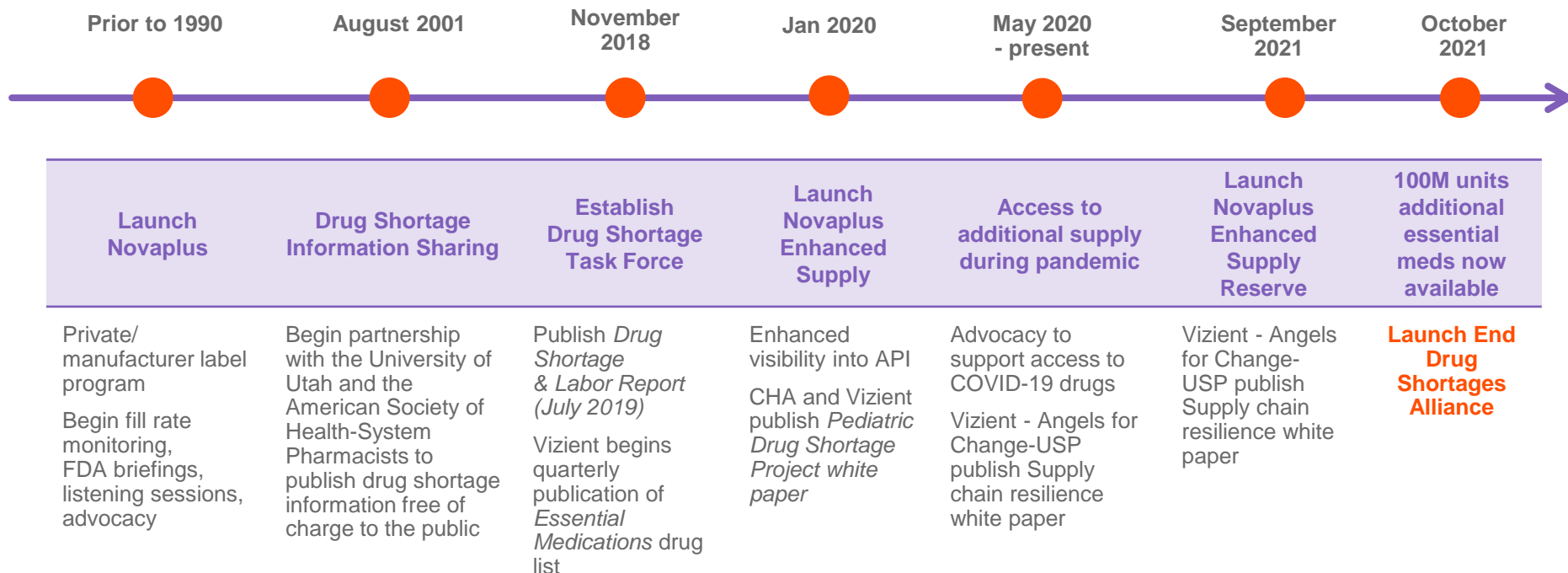


Support commitment and transparency



Advocate for better access to life-saving medications

Pharmacy journey to end drug shortages



Improve access, improve life.

We are a collaboration of select health system, supply chain, industry and other stakeholders dedicated to solving pharmaceutical supply challenges by increasing transparency

End Drug
Shortages
Alliance



What we do	Areas of focus	Target members
Connect Bring together representatives with the common interest to end drug shortages	Improving access to essential medications through: <ul style="list-style-type: none">• Transparency and redundancy• Quality• Production of additional supply	Health systems <ul style="list-style-type: none">• NES Reserve participants• Target members who achieve 75-85% Novaplus compliance Suppliers of essential medications (generic injectables) Other key industry stakeholders and advocates

Using Data and Expertise to Inform Sourcing Decisions

Sourcing strategies begin with prioritizing essential medications

Essential Medications Review

Identifies drugs that, if unavailable, would impact hospital's ability to deliver immediate high-quality care

- Developed / reviewed quarterly by Vizient Center for Pharmacy Practice Excellence
- Represents 234 unique drugs, 5 categories
 - Acute treatment drugs with no alternatives
 - Chronic treatment drugs with no alternatives
 - High impact drugs
 - Pediatric impact
 - Antibiotic resistance
- Additional list of antidotes now included



Vizient action steps:

- ✓ Foundation for initiating sourcing strategies that prioritize production of these essential medications
- ✓ Continue efforts to advocate and endorse public policies that facilitate expanded supply and increased quality of these essential medications
- ✓ Focus on clinical mitigation strategies on medications that are classified as “essential”

Expanded capabilities to drive increased transparency

COVID-19 Manufacturing Location Analysis

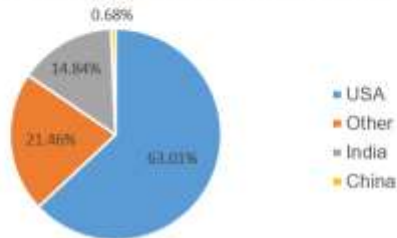
Assessing the potential impact of COVID-19 on the pharmaceutical supply chain by analyzing geographic data collected from the RFP process

From the data provided by manufacturers in all submitted RFPs spanning from 2018 to the present, an analysis was conducted on medications that would potentially be affected by COVID-19 in China. Annual spend data and contract status was included for each reported NDC.

For NDCs currently on contract with Vizient: The percentage of NDCs manufactured in China compared to other countries

Out of the NDCs on contract with a bid since 2018, NDCs manufactured in China only make up 0.68% of the total.

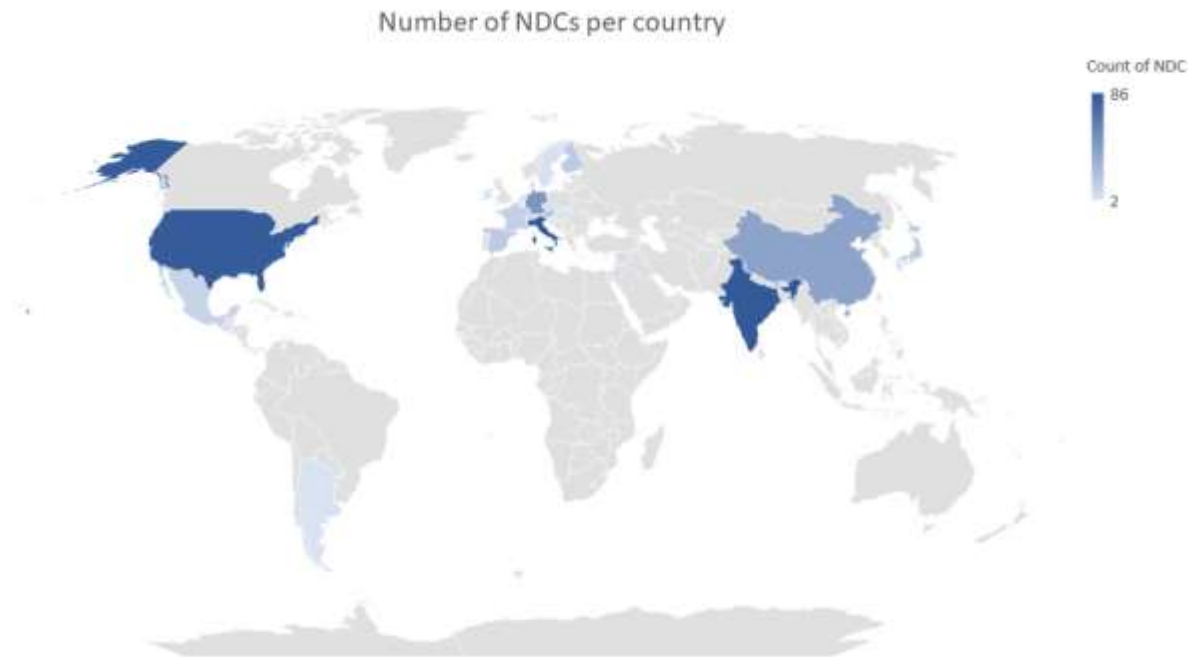
Percent of NDCs manufactured by country (N=438)



March 2020

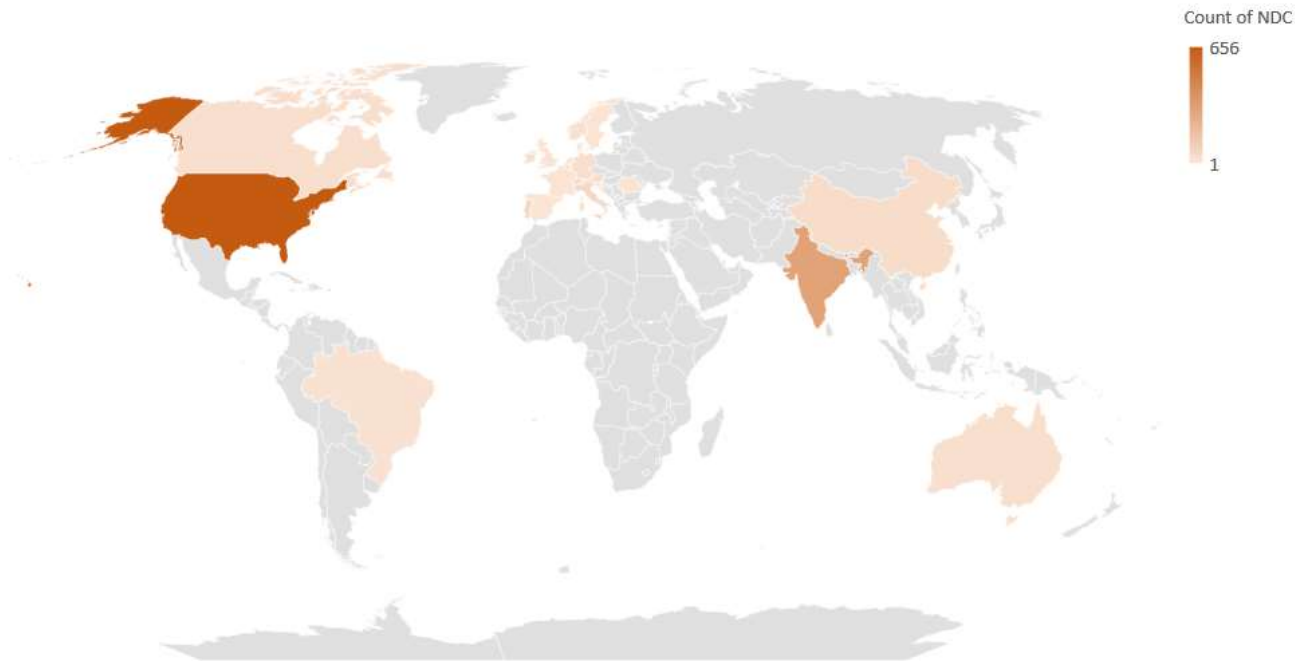
- Vizient non-financial award criteria
 - Integral, long-standing part of sourcing strategy
 - History of supply interruptions; FDA warning letters
 - Detailed information concerning the location of production (API and FDF) and other insight into quality manufacturing practices are essential to strategic supply decision making.
 - Annual quality attestations from suppliers
- The industry must work towards making the collection of this information more efficient, more accessible, and more comprehensive.

Vizient active pharmaceutical ingredient (API) location map



Manufacturing and/or final fill location

Number of NDCs per country



Addressing Quality Issues to Improve the Supply Chain



[https://newsroom.vizientinc.com/vizient-and-riscs-announce-pilot-program-to-improve-pharmaceutical-supply-chain-resilience.htm?pressrelease;](https://newsroom.vizientinc.com/vizient-and-riscs-announce-pilot-program-to-improve-pharmaceutical-supply-chain-resilience.htm?pressrelease)
https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/pediatric_oncology_whitepaper_2021.pdf

How Could Vizient Use QMM Ratings?

- **Include expanded metrics in award process**
 - Utilize in non-financial evaluation criteria
 - Make some aspect of quality rating more visible to providers
- **Validation/corroboration of quality information received from other sources**
- **Where quality and capacity are lacking, try to encourage greater participation/competition**
 - Could other parties assist with requirements to receive approval (e.g. literature reviews)?
- **Increase understanding of providers regarding the relevance of quality and the need for investment**
 - How does quality of product translate into patient safety?
 - Will higher quality products result in few adverse event?
- **However, entire health system, not just providers, must share in the investment to support improved quality**

Questions Related to Implementation

- How is transparency encouraged, required, improved? (e.g. Irvine, California plant)
- Transparency across all aspects of manufacturing, quality is required
- Implementation requires significant educational support from FDA
 - What does a strong rating mean?
 - Is it unsafe to use a lower rated product?
 - What if all suppliers have similar, lower ratings?
 - Need to know what products (i.e. NDCs) are being manufactured at each facility
- How do we ensure increased investment (higher product costs) translates to true quality improvements?



Communication and Education Considerations

- **How best to describe a highly-rated facility while maintaining confidence in the drug supply chain?**
- **How best to communicate that a product is safe and efficacious, even if a facility does not receive a high rating?**
- **How will complaints from providers or consumers regarding a specific product be considered? What about resolution of those complaints?**
- **Will the rating system reflect the likelihood that a product is consistently available?**
- **How will facility preparedness be considered (e.g., contingency plans for different potential disruptions)?**

Questions and discussion for Panel

Let's work together



Dan Kistner, PharmD

Daniel.Kistner@vizientinc.com

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