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

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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

3,100
Pharmacy program participants

$90B+
Pharmaceutical spend

$3B
Novaplus® private label

12,000
Contracted products and services

Supporting members in the management of COVID-19 and future pharmacy spend

3.1%
July 2021 projected drug price inflation rate

100M
Additional units of essential medications made available through Novaplus Enhanced Supply Program

$335M
Inventory cost avoidance for our members

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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.

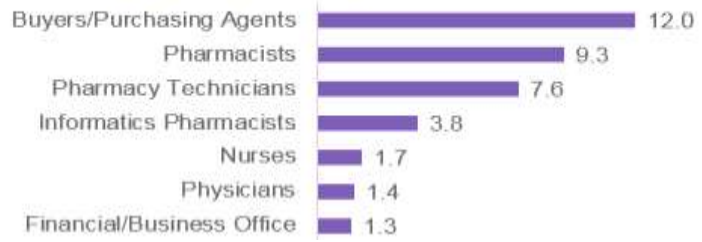
$345 million per year

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

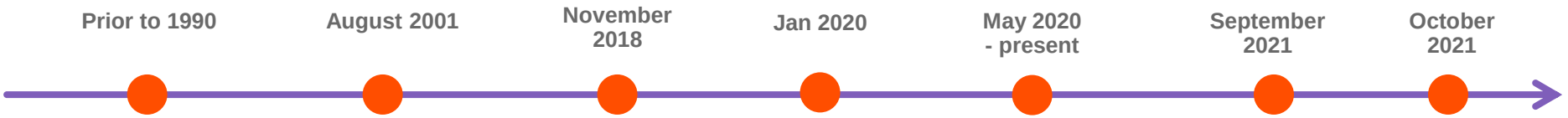
Identify essential medications

Drive additional supply into the market

Support commitment and transparency

Advocate for better access to life-saving medications

Pharmacy journey to end drug shortages



Launch Novaplus	Drug Shortage Information Sharing	Establish Drug Shortage Task Force	Launch Novaplus Enhanced Supply	Access to additional supply during pandemic	Launch Novaplus Enhanced Supply Reserve	100M units additional essential meds now available
Private/ manufacturer label program Begin fill rate monitoring, FDA briefings, listening sessions, advocacy	Begin partnership with the University of Utah and the American Society of Health-System Pharmacists to publish drug shortage information free of charge to the public	Publish *Drug Shortage & Labor Report (July 2019)* Vizient begins quarterly publication of *Essential Medications* drug list	Enhanced visibility into API CHA and Vizient publish *Pediatric Drug Shortage Project white paper*	Advocacy to support access to COVID-19 drugs Vizient - Angels for Change-USP publish Supply chain resilience white paper	Vizient - Angels for Change-USP publish Supply chain resilience white paper	**Launch End Drug Shortages Alliance**

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Improve access, improve life.

End Drug Shortages Alliance

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

What we do	Areas of focus	Target members
Connect Bring together representatives with the common interest to end drug shortages **Collaborate** Share insights and expertise to solve supply challenges **Commit to change** Support and acknowledge improvements made as a result of the Alliance work	**Improving access to essential medications through:** • Transparency and redundancy • Quality • Production of additional supply	**Health systems** • 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

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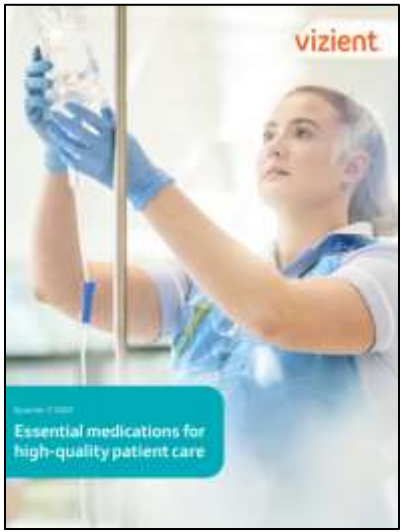
Sourcing strategies begin with prioritizing essential medications

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"

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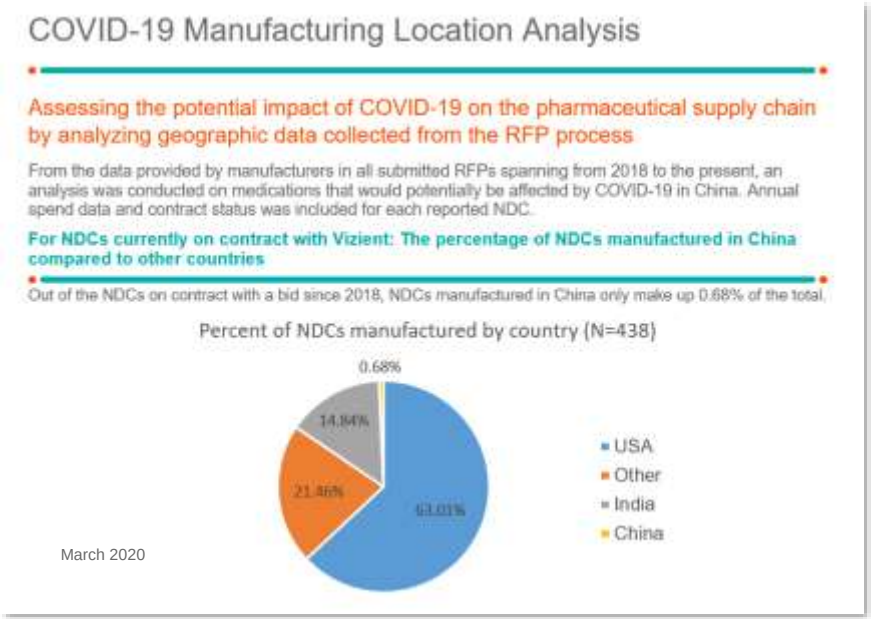
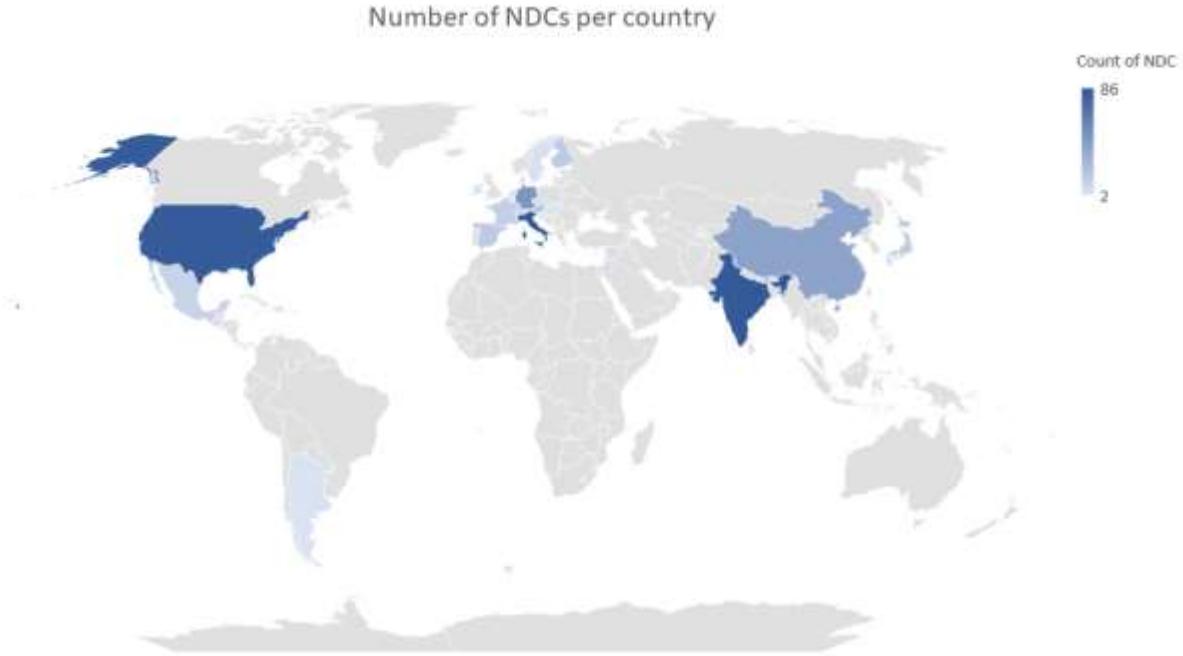
Expanded capabilities to drive increased transparency

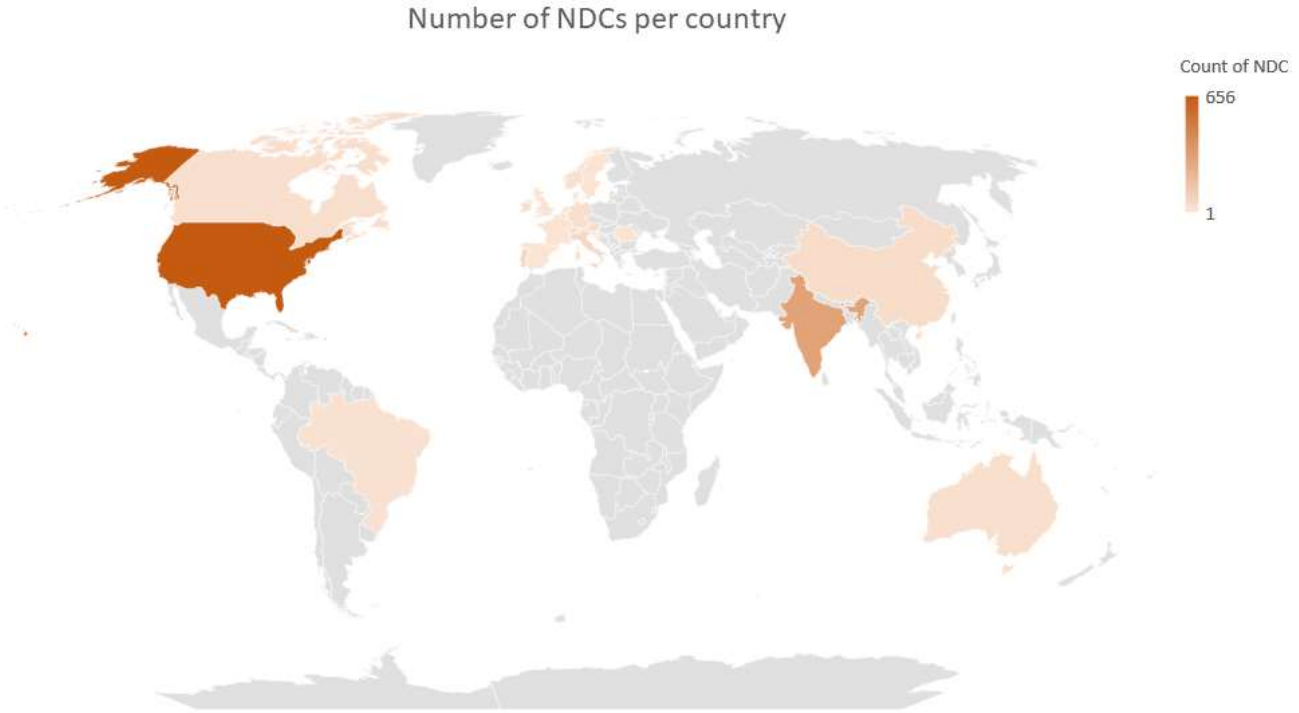


- Vizient non-financial award criteria
  - Integral, long-standing part of sourcing strategy
    - History of supply interruptions; FDA warning letters
  - Detailed information concerning the location of production (API and FDF) and other insight into quality manufacturing practices are essential to 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



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Addressing Quality Issues to Improve the Supply Chain

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Vizient and RISCS Announce Pilot Program to Improve Pharmaceutical Supply Chain Resilience

Irving, TX, and Denver, CO—May 4, 2022—Vizient Inc. and RISCS, Inc. today announced a joint pilot program aimed at enhancing assurance of pharmaceutical supply. Once implemented, the program would use a rating system to enable the evaluation of critical aspects of a resilient supply chain and provide increased transparency.

During the pilot, pharmacy suppliers will be asked to provide key information on their supply chains through the request-for-proposal process. The information provided will enable visibility into supply chain aspects such as redundancy in raw material supply, available production capacity and production flexibility, inventory practices, location differentiation and geopolitical risks.

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?**


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Drug Shortage Stewardship

Alprostadil injection, Cisatracurine injection, Daunorubicin injection, Desmopressin injection, Lauroxerin injection, Streptozocin injection

Situation

Background

Assessment and recommendations

Manufacturers and wholesalers

Food and Drug Administration

Group Purchasing Organizations

Clinical and providers

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

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Let’s work together

Dan Kistner, PharmD

Daniel.Kistner@vizientinc.com