

# Drug Shortages 101

Lexi Hayes BSc(Pharm), RPh  
Island Health Drug Shortages Pharmacist

# Presenter Disclosure

- ▶ Presenter's Name: Lexi Hayes
- ▶ I have no current or past relationships with commercial entities
- ▶ Speaking Fees for current program:
  - I have received a speaker's fee from CSHP-BC for this learning activity

# Commercial Support Disclosure

- ▶ This program received no financial or in-kind support from any commercial or other organization.

# Learning Objectives

**By the end of this session, the participant will be able to:**

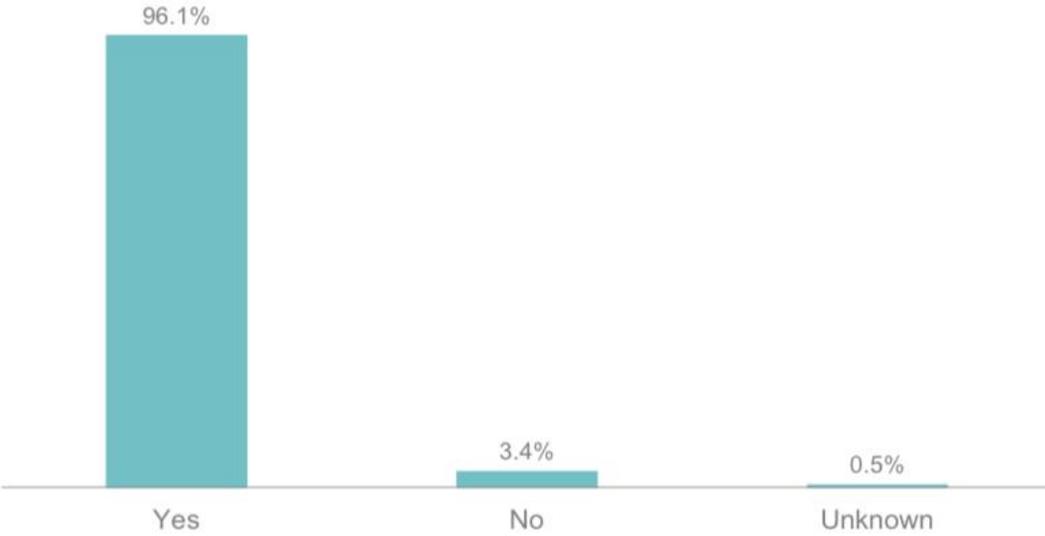
- ▶ To list causes of drug shortages and explain why they are an ongoing problem
- ▶ To list potential options available to mitigate drug shortages
- ▶ To identify the risks associated with drug shortages
- ▶ To explain how the Pharmacy team works together to find solutions to drug shortages that affect Island Health.
- ▶ To explain how COVID-19 affected drug shortages within Island Health

# Poll

- ▶ Yes or No: do drug shortages cause you stress?

# Pharmacist stress associated with shortages:

Do drug shortages/recalls cause you stress?

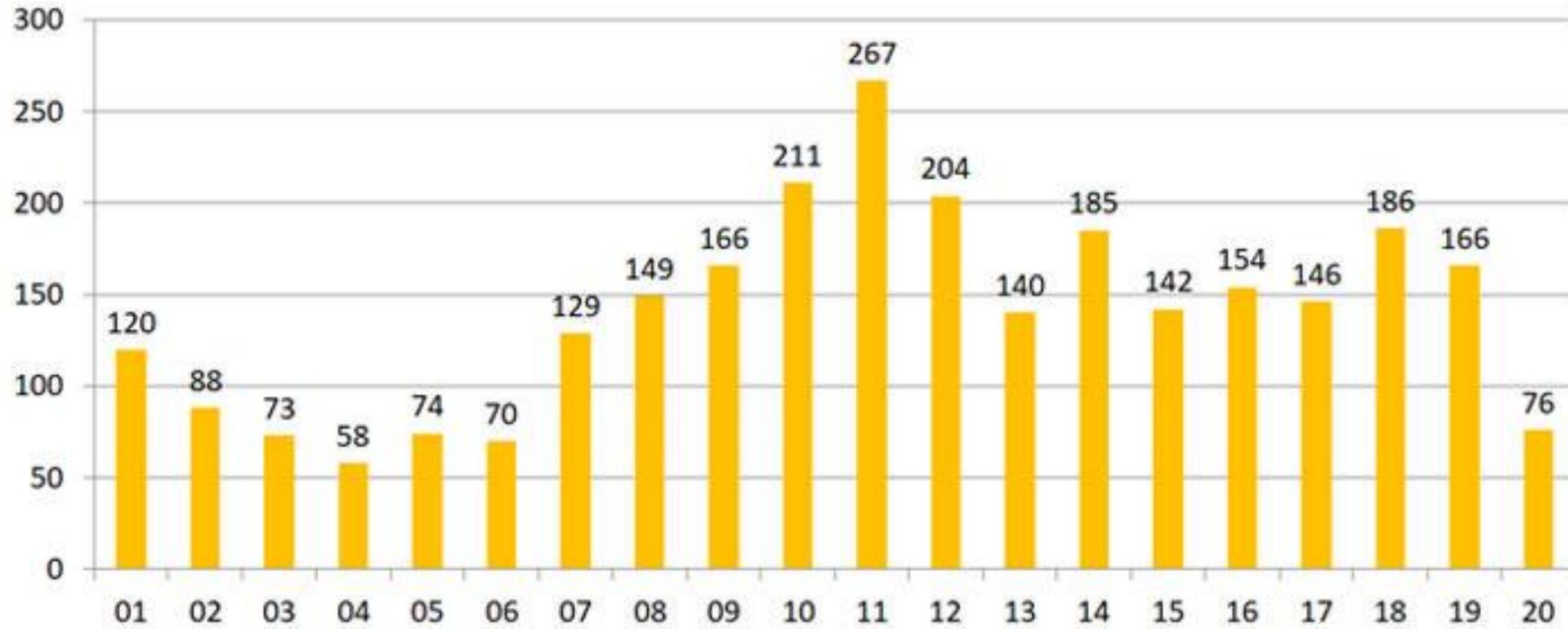


Source: Canadian Pharmacists Association. CPhA Drug Shortages and Recalls Survey 2018; 2018 Nov [cited 2020 Sept 22]. Available from: URL: <https://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/CPhADrugShortagesandRecallsSurvey2018.pdf>

# Why are drug shortages an ongoing problem?

- ▶ Drugs shortages have long been an issue for pharmacists
  - There has been a dramatic increase in drug shortages over the past 10 years
- ▶ Due to the increase in Drug Shortages over the past decade, there has been a national focus in Canada on reporting, tracking and mitigating shortages
- ▶ The causes of Drug Shortages are complex and multifactorial.

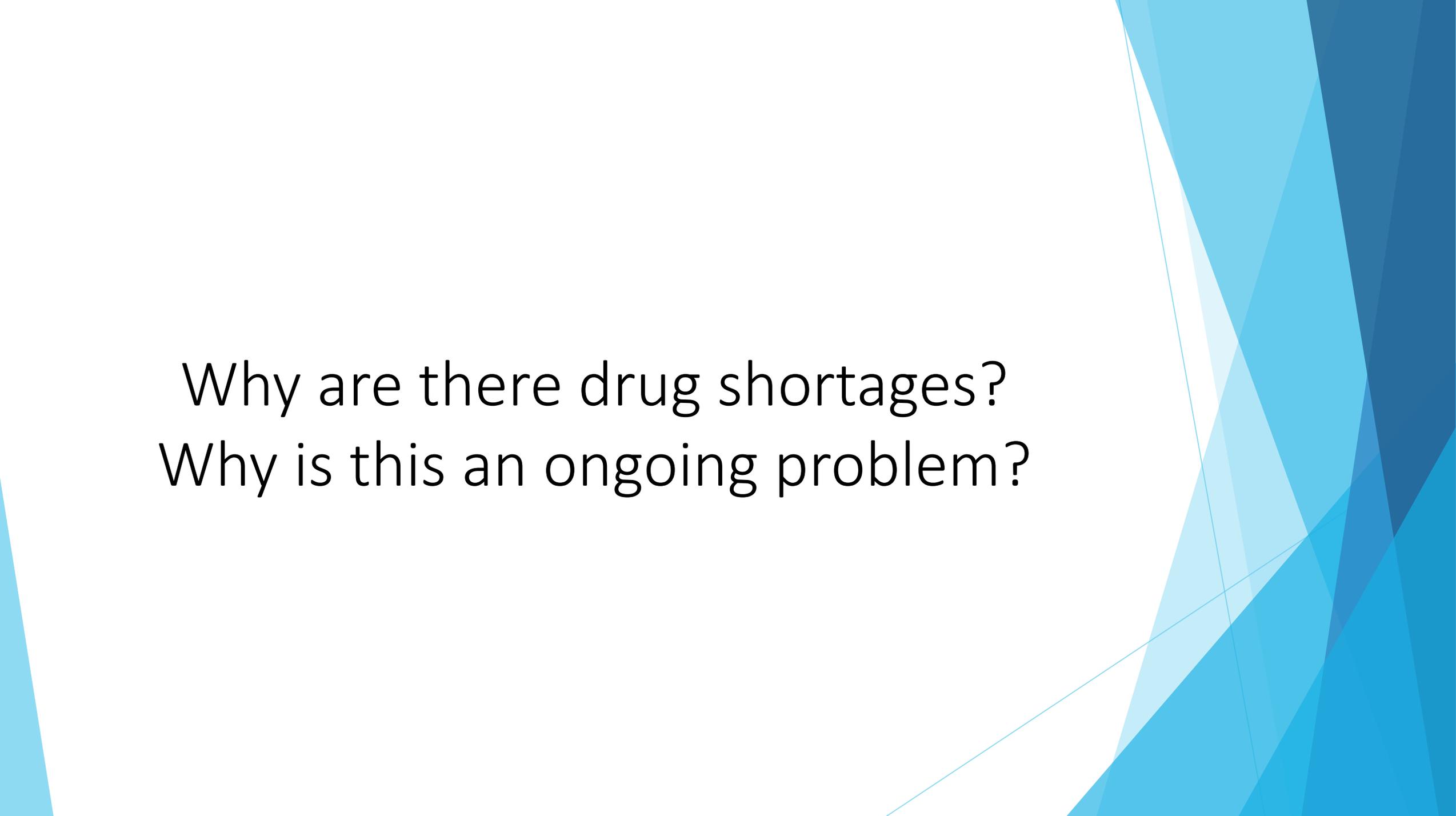
## National Drug Shortages: New Shortages by Year January 2001 to June 30, 2020



**Note:** Each column represents the number of new shortages identified during that year.

University of Utah Drug Information Service

Source: ASHP. Drug Shortages Statistics; 2020 [cited 2020 Sept 22]. Available from: URL: <https://www.ashp.org/Drug-Shortages/Shortage-Resources/Drug-Shortages-Statistics>

The background features abstract, overlapping geometric shapes in various shades of blue, ranging from light sky blue to deep navy blue. These shapes are primarily located on the right side of the frame, creating a modern, layered effect.

Why are there drug shortages?  
Why is this an ongoing problem?

# Supply

## Active Product Ingredient (API) issues

- ▶ Sole source supply of API
- ▶ Contamination of API

## Supply issues unrelated to API

- ▶ Excipients
- ▶ Component
- ▶ Packaging

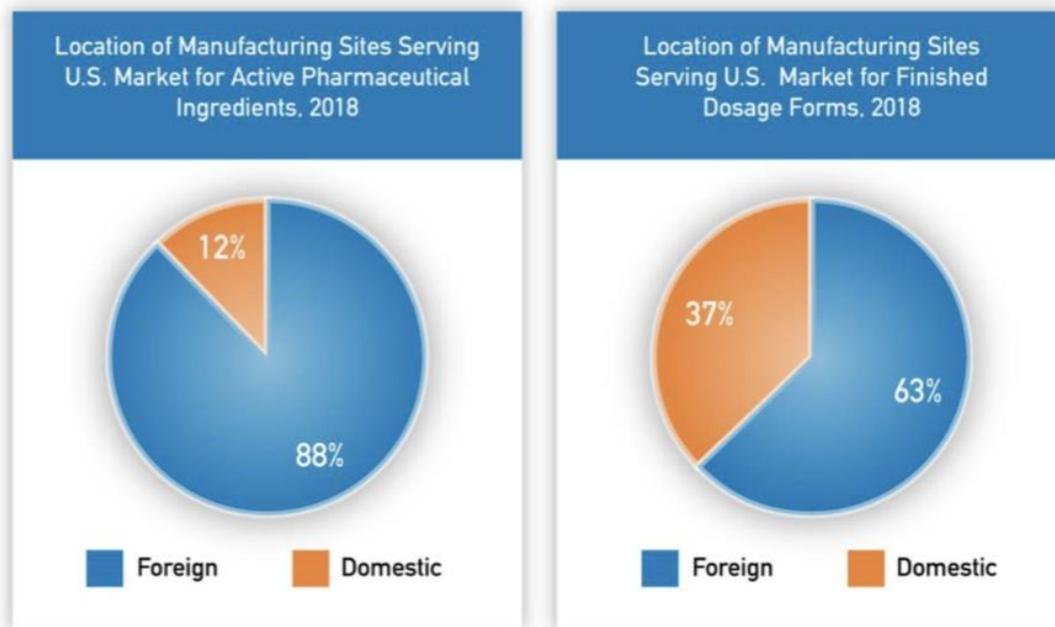


Figure 3. In 2018, the majority of manufacturing sites making active pharmaceutical ingredients and finished dosage forms for the U.S. market were located abroad.<sup>20</sup>

Source: U.S. Food and Drug Administration. Drug Shortages: Root Causes and Potential Solutions; 2020 Feb 21 [cited 2020 Sept 22]. Available from: URL: <https://www.fda.gov/media/131130/download>

# Supply

## Increased demand for medication

- ▶ Pandemic
- ▶ New indication
- ▶ Emerging markets
- ▶ Pressure on supply due to backorder of another drug

## Importing issues

- ▶ Regulations

## Natural Disaster

- ▶ Production decreased or stopped

# Manufacturing

## Manufacturing Process

- ▶ Long lead time, delays in production
- ▶ Lack of alternate manufacturing options, unable to scale up
- ▶ Specialized processes
- ▶ Contamination during production
- ▶ Changes in procedures, regulations
- ▶ Voluntary recalls

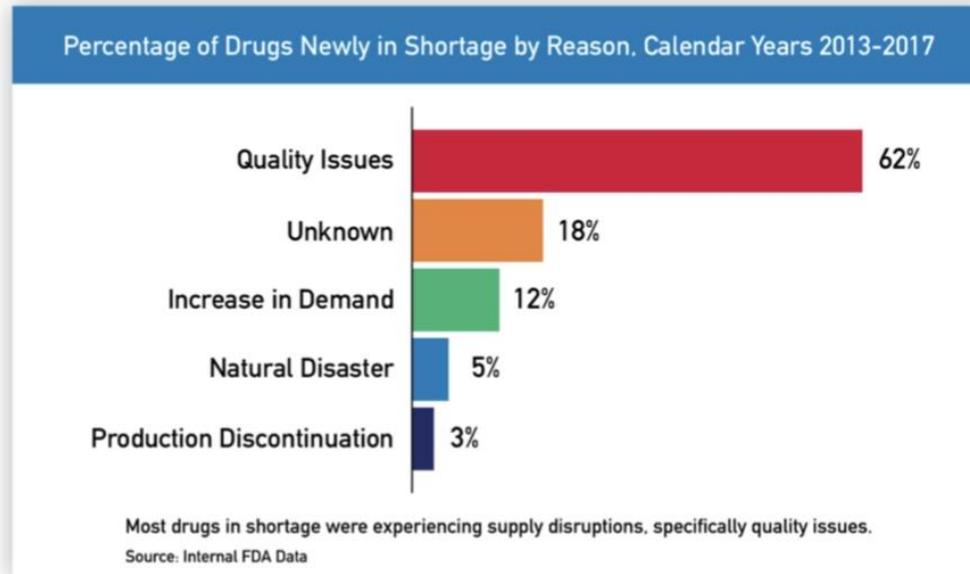


Figure 6. Of 163 drugs that went into shortage between 2013 and 2017, 62 percent went into shortage after supply disruptions occurred that were associated with manufacturing or product quality problems.

Source: U.S. Food and Drug Administration. Drug Shortages: Root Causes and Potential Solutions; 2020 Feb 21 [cited 2020 Sept 22]. Available from: URL: <https://www.fda.gov/media/131130/download>

# Quality Assessment (QA)

## Raw material QA

- ▶ API
- ▶ Excipients

## QA during or after manufacturing process

- ▶ Sterility, particulates, impurities

# Contracting issues

Reliance on sole source supplier

Manufacturer

- ▶ API

Group Purchasing Organisation (GPO)

- ▶ Sole source manufacturer

# Economic Factors

## Mergers and Acquisitions

- ▶ Decreased competition
- ▶ Consolidation of drug companies; no redundancy

## Drug discontinuations

- ▶ Low cost or demand
- ▶ Unprofitable

## Bankruptcy

# Other

## Transportation

- ▶ Timing
- ▶ Cold chain

## Communication

- ▶ Supply disruption not revealed early enough

## Inventory Control

- ▶ “Just-in-time” ordering of stock; no buffer supply
- ▶ Stockpiling

- ▶ There are a multitude of issues contributing to Drug Shortages, none of which can easily be resolved.
- ▶ Drug Shortages are here to stay for the foreseeable future.

# How can we mitigate drug shortages?

Most drug shortages cannot be prevented at the hospital level

- ▶ Manufacturers, International and National governments and Group Purchasing Organisations have the ability to prevent some shortages by changing practices

# How can we mitigate a drug shortage within the hospital?

Change brand

- ▶ EPINEPHrine

Change size

- ▶ midazolam

Change concentration

- ▶ sodium chloride

Change format

- ▶ fluorescein

Change to another drug in same class

- ▶ ceFAZolin

Change to another drug in another class

- ▶ acamprosate

Change to non-formulary option

- ▶ timolol

Restrict use to certain patient groups/prescribers

- ▶ belladonna & opium

## Compound

- ▶ iodine eyedrops
- ▶ cotrimoxazole
- ▶ heparin

## Special Access Programme (SAP)

- ▶ sterile talc

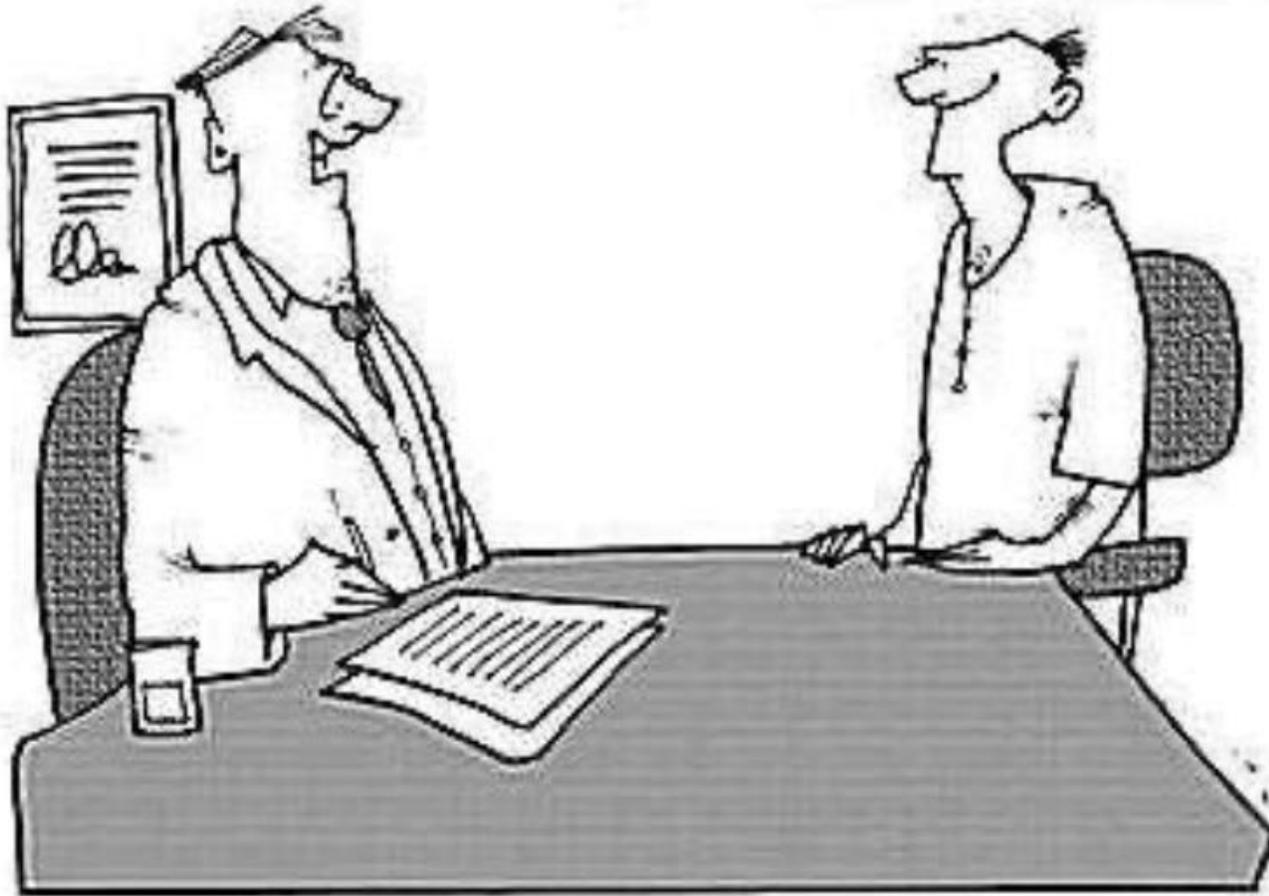
## Exceptional Importation and sale of drugs in relation to COVID-19: Tier 3 drug Shortages

- ▶ acyclovir

## Food

- ▶ dextrose

Sometimes there is no solution



***There's a drug shortage. I'm thinking of replacing your meds with eight hugs a day before & after meals!***

# What are the risks associated with drug shortages?

- ▶ Med safety issues: change in brand - look-alike sound-alike
- ▶ Change in labelling
- ▶ Change in size or concentration
- ▶ Change in the way the product is administered: nursing or physician not familiar
- ▶ When drug shortage has resolved, chance for error when mitigation strategy has been reversed

- ▶ Alternate can be less effective, not first-line choice
- ▶ Increased side effects or narrower margin of safety
- ▶ Poor outcome, increased complications
- ▶ Compounding error
- ▶ Sterility issues
- ▶ Procedures delayed, nontreatment
- ▶ Patient may have to stay in hospital longer
- ▶ Mortality

## Additional Considerations

### Occupational Health and Safety cost

- ▶ Increased workload for CIVA technicians leading to repetitive strain injury

### Clinical cost

- ▶ Clinicians spending time dealing with shortages instead of with patients

### Financial cost

- ▶ Extra staff, alternate drugs

# How does the Pharmacy team work together to find solutions to drug shortages that affect Island Health?

## Who is involved?

### Drug Shortages Team

- ▶ Includes Medication Use Management Office (Drug Shortages Pharmacist), Purchasing Office, Pharmacy Stores, Managers, Inventory Technicians, Site Coordinators, Medication Safety Pharmacist, RxIT, Pharmacy HUB
  - Drug Shortages meetings every week, alternates between the larger group and just the managers.

## How do we know there is a drug shortage?

Drug shortages are identified by:

- ▶ A drug is ordered and is listed as on backorder through supplier; added to the Drug Shortages SharePoint by purchasing office and is tracked
- ▶ Attending monthly Drug Shortages teleconferences with other Health Authorities, Provincial and National groups; upcoming and ongoing drug shortages discussed
- ▶ Physician, pharmacist or technician - heard it through the grapevine
- ▶ Can be found on [www.drugshortagescanada.ca](http://www.drugshortagescanada.ca), updated daily. Mandatory reporting required by manufactures

## What do we do when a drug shortage has been identified?

- ▶ If a drug could become or is a potential issue, discussion happens at drug shortages meeting, over email, over phone
  - Determine if communication required, via memo or email
  - Determine if stakeholder/expert feedback required
- ▶ Has this been a problem in the past? Orbiting shortages

## Information gathering:

- ▶ If more feedback or information required, engagement with Clinical Pharmacy Specialists, Nurses, Physicians, to gather information and determine best course of action.
- ▶ Ask counterparts at other Health Authorities, bring up at monthly meetings
- ▶ CSHP Drug Shortages eForum (QID)

## Communication

- ▶ Feedback/options are taken back to managers for decision on plan of action.
- ▶ Once plan has been determined, memo is drafted, edited and then must be approved by managers.
- ▶ The memo may be sent out immediately, or held back. In some instances, shortage resolves before it has to be sent out.

Memo is sent to all sites within Island Health

- ▶ Each drug shortage may affect each site differently

Track shortage and when the backorder has resolved, and supply is stable, memo is reversed.

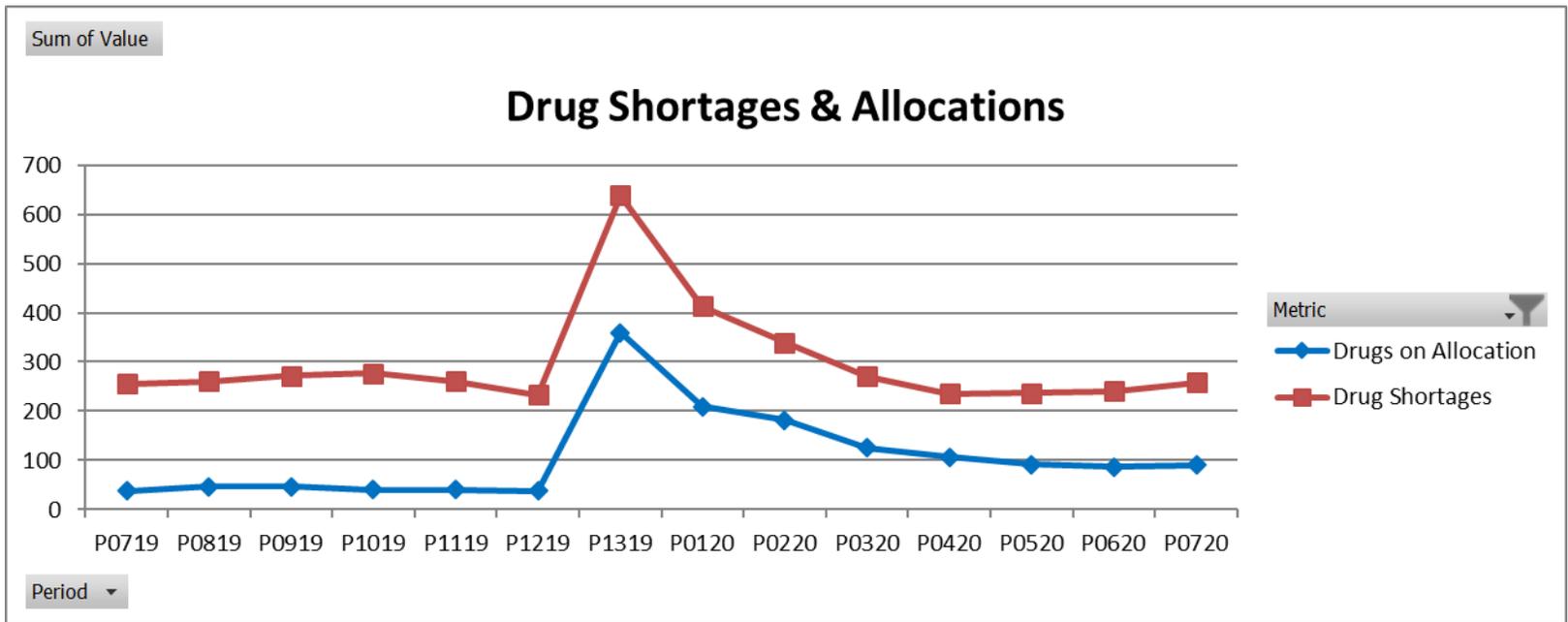
**DID YOU SEE THE MEMO?**

**I'LL GET YOU ANOTHER COPY OF  
THAT MEMO**

memegenerator.net

# Propofol Case Study: Drug Shortages in COVID-19 Pandemic Times

- ▶ During the pandemic many medications became short due to increased demand
- ▶ Supply of critical care medications such as propofol, ketamine, midazolam, dexmedetomidine, succinylcholine, rocuronium, cisatracurium, morphine, fentanyl, and norepinephrine in particular were under supply constraint
  - Patients with COVID-19 infections can consume these medications at double or triple the rate of other intensive care patients



## Focus on propofol:

Island Health carries propofol 1%, 20 mL, 50 mL and 100 mL

Restrictive allocations placed on propofol 1% by manufacturers to preserve supply and prevent stockpiling

At the rate that patients with COVID-19 go through propofol, hospitals around the country became concerned that there would be a shortfall

## What did we do?

- ▶ Start keeping track of supply of propofol on SharePoint
- ▶ Order different brands - product review required
- ▶ Order all allocations, order in extra supply directly from manufacturer
- ▶ Higher level tracking of stock; special reports created to focus on propofol and other drugs at risk.
- ▶ Predictive modeling of use of critical care medications used in patients with COVID-19 infections created by Northern Health and shared with the other BC Health Authorities
- ▶ Ordered supply of foreign product, different strength

## Propofol 2% - The solution to one problem, the potential cause of another

- ▶ Many medication safety issues, potential for medication errors

# Risk: an unfamiliar high-alert medication with the potential for a 2-fold overdose

## Questions to answer:

- ▶ Where is it used?
- ▶ How much is used?
- ▶ By what populations?
- ▶ How is it administered? What clinicians are involved?
- ▶ Are updates required for pumps, drug libraries, IV monograph or Clinical Order Sets?
- ▶ Who needs to be engaged for feedback?
- ▶ What safeguards can be put into place to mitigate risk?
- ▶ When will the change happen?
- ▶ How will the change be communicated?

## Engagement between

- ▶ Medication Safety Pharmacist, Medication Safety Nurses
- ▶ Drug Shortages Pharmacist
- ▶ Pharmacy Managers
- ▶ Clinical Pharmacy Specialists
- ▶ IV Monograph/Clinical Order Set Pharmacist
- ▶ Research and Sterile Products Pharmacist
- ▶ Biomedical Engineering
- ▶ Professional Practice, Risk Assessment
- ▶ Anesthetists, Intensivists, Critical Care Nursing
- ▶ Purchasing, Stores

# Resources

- ▶ <https://cshp.ca/drug-shortages>
- ▶ <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages.html>
- ▶ <https://www.drugshortagescanada.ca/>
- ▶ <https://medsask.usask.ca/professional-practice/drug-shortages.php>
- ▶ <https://www.ashp.org/Drug-Shortages>
- ▶ <https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages>
- ▶ <https://www.cadth.ca/symposium2018/canadas-multi-stakeholder-approach-drug-shortages>
- ▶ [https://www.cdhowe.org/sites/default/files/attachments/research\\_papers/mixed/Commentary\\_515.pdf](https://www.cdhowe.org/sites/default/files/attachments/research_papers/mixed/Commentary_515.pdf)
- ▶ <http://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/DrugShortagesGuide.pdf>
- ▶ <https://www.canada.ca/en/public-health/services/emergency-preparedness-response/national-emergency-strategic-stockpile.html>
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Questions?

