Gaps in Your Postmarket Safety Net for Medical Devices

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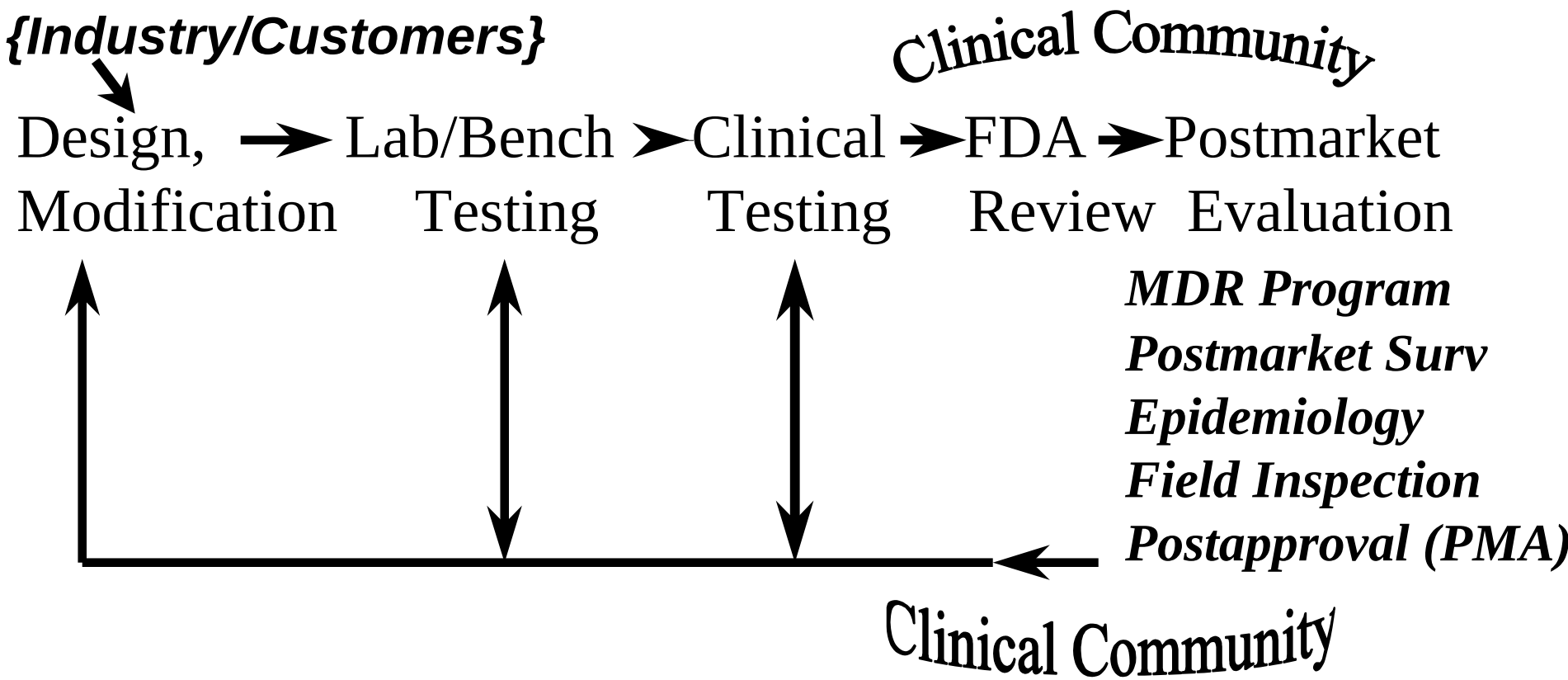
Today's Objectives

- Describe methods of device postmarket surveillance
- Challenges in assessing adverse events
- The complicating factors of medical error
- The holes in the Safety Net
- A vision of the future

What you might not know...

- Medical devices are ubiquitous in health care (from Exam Gloves to In Vitro Diagnostics to Implantable Cardioverter Defibrillators to Magnetic Resonance Imaging Machines)
- Recognition of device errors or adverse events presents a series of challenges
- Under-recognition, under-reporting, and the “blame game” continue to act as obstacles

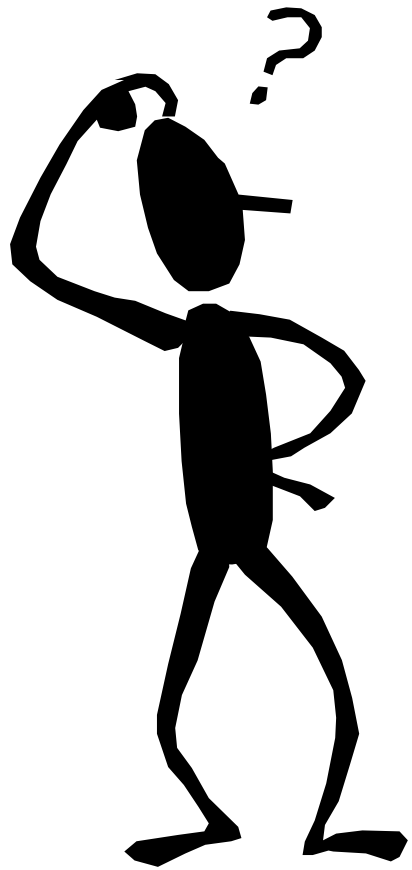
From Design to Obsolescence: Medical Devices and Center for Devices and Radiological Health, FDA



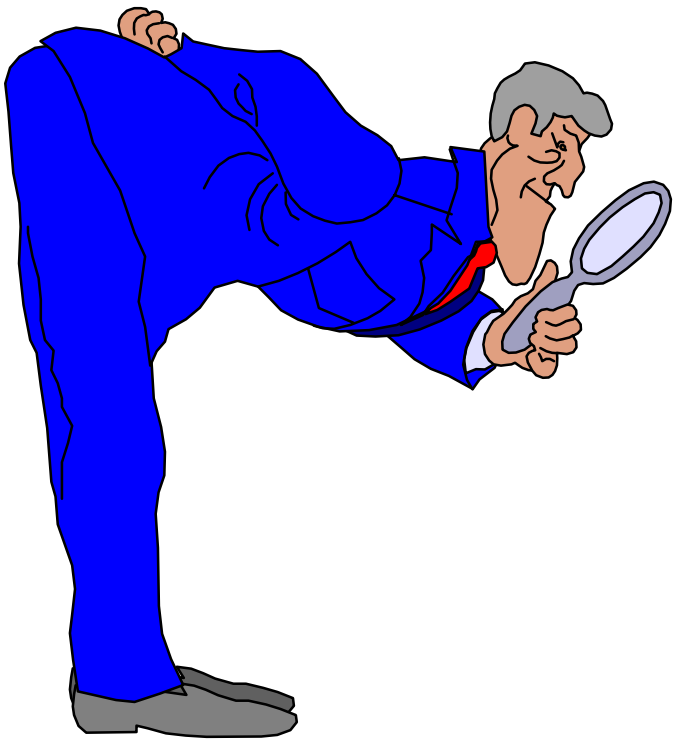
'Design' ⟶ Device evolution ⟶ 'Obsolescence'

Questions of Interest in the Postmarket Period

- Long term safety
- After clinical trials, performance of device in community practice
- Change of user setting (e.g., hospital to home)
- Unusual pattern of adverse events not requiring product recall

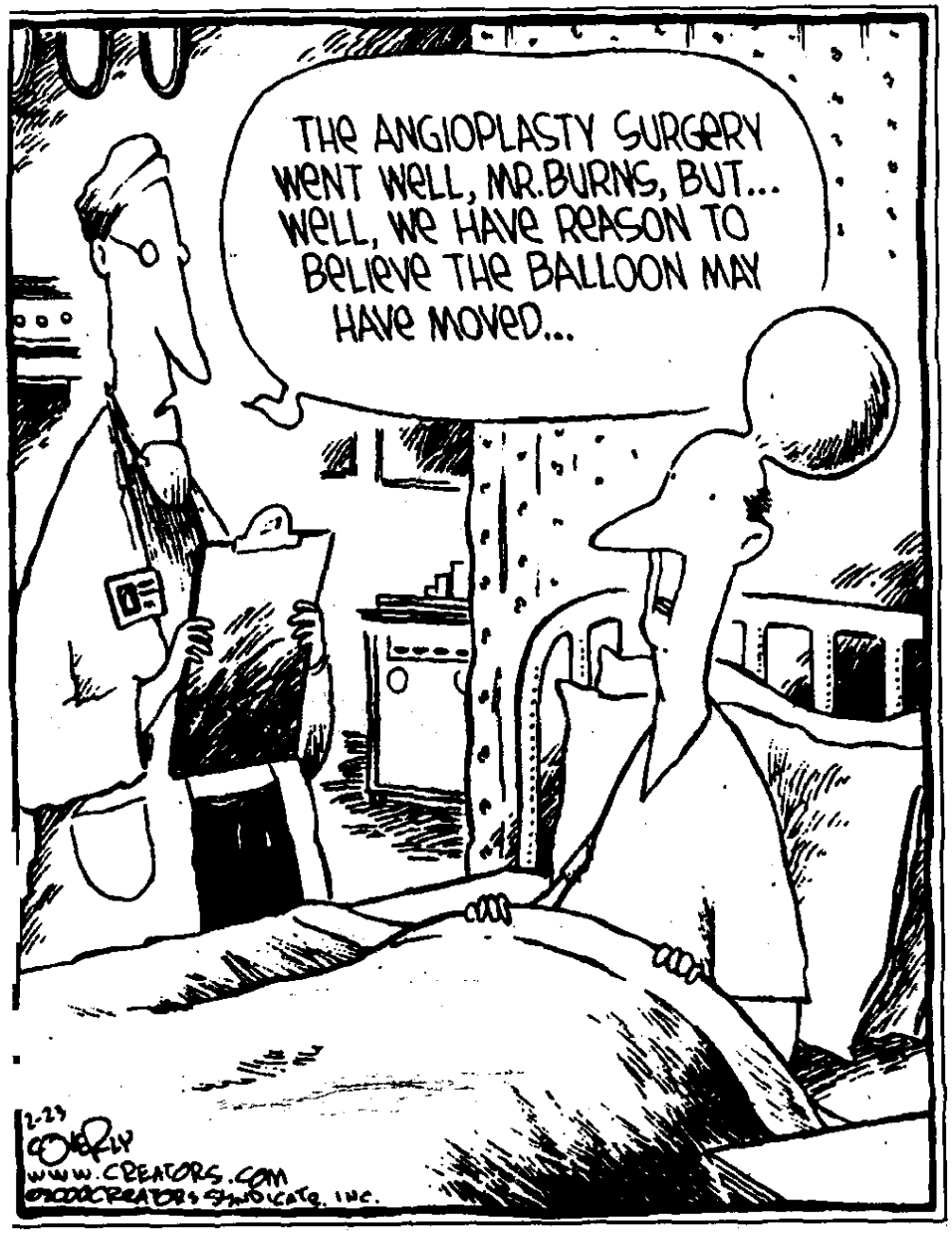


Adverse Event Reporting: FDA's MedWatch Program



- **Mandatory Reporting:**
  - **Manufacturers must (by law) report deaths and serious injuries or malfunctions (near incidents) if a medical device may have caused or contributed to the event**
  - **All user facilities (hospitals, nursing homes, etc.) must report deaths to FDA and serious injuries to manufacturers**
- **Voluntary Reports encouraged from health professionals**

SPEED BUMP DAVE COVERLY



Example of MDR Report - Death Manufacturer Report

- **Mfr 22-FEB-2000: FOLLOWING A LEFT HEART CATHETERI-ZATION PROCEDURE, AN ANGIO-SEAL DEVICE WAS DEPLOYED IN THE RIGHT FEMORAL ARTERY WITHOUT REPORTED DIFFICLUTIES. APPROX 5 DAYS LATER, THE PT BECAME UNSTABLE. A FEMSTOP WAS APPLIED TO THE FEMORAL ARTERY, FLUID VOLUME REPLACEMENT WAS GIVEN, AND PLATELET RED CELLS ORDERED TO REPLACE VOLUME LOSS. THE VASCULAR SURGEON WAS CALLED TO ASSES THE EVENT. THE PT WAS TAKEN TO SURGERY, THE FEMORAL BLEED WAS REPAIRED AND A RETROPERITONEAL HEMATOMA WAS EVACUATED...REVEALING AN OPEN PUNCTURE SITE IN THE RIGHT ILIOFEMORAL ARTERY. SUDDENLY, THE PT DEVELOPED SEVERE HYPOTENSION, DEEP CYANOSIS, AND THEN AGONAL RHYTHM AND THE PT EXPIRED. IT SHOULD BE NOTED THAT THE PHYSICIAN HAS STATED THAT AN ERROR IN DEPLOYMENT WAS MADE BY THE OPERATOR; IT WAS NOT A DEVICE FAILURE, BUT AN OPERATOR FAILURE.**

Unique Aspects of Device Events

- Lack of standard nomenclature for devices
- Often, these events represent numerators, with no clear denominator available
- Operator involvement and human factors issues inherent in virtually every event
- Complex multi-device situations are common leading to complex evaluation
- ***Information in reports often limited***

The St. Jude Silzone Heart Valve

- Mechanical valve: silver coated to reduce incidence of a known complication: endocarditis
- Already 30,000 have been distributed
- High rate of thromboembolic events in one U.K. clinical center
- Alert by U.K. Medical Devices Agency
- Available data has significant flaws
- What should FDA do?

Potential Actions for FDA

- **Judge problem of no significance**
- **Have company notify**
- **Release an FDA Advisory/Alert**
- **Collect more data under regulatory authority**
- **Force off market:**
- ***Summer 2000: St. Jude performed recall***

The Fundamental Problem?

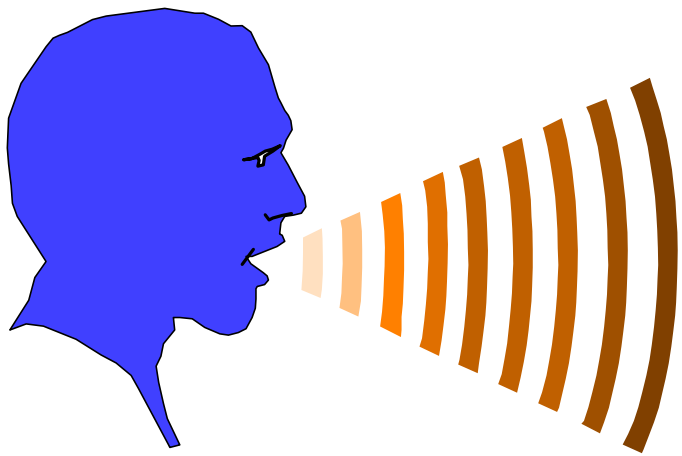
For many devices, the lack of systematic data in the postmarket period hampers reasonable, science-based decision-making

THE MEDICAL DEVICE SURVEILLANCE NETWORK (MeDSuN)

WHY CHANGE USER REPORTING?

- **Underreporting / lack of quality data**
- **Lack of connection to clinical facilities**
- **FDA's current system is dominated by manufacturer reporting**
- **Food and Drug Modernization Act 1997**

Sentinel Reporting
FDA's Pilot Program



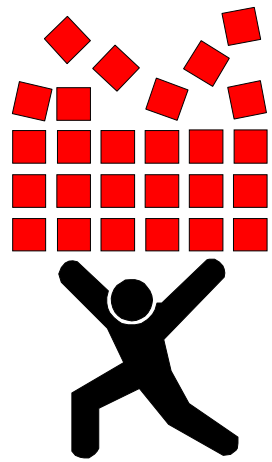
- "Sample" of user facilities committed to reporting
- Well educated and well monitored
- Regular feedback on performance or device information

Reporting Barriers

LIABILITY

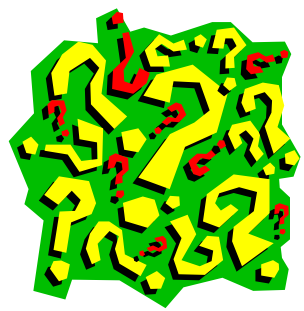
Recognition

FEEDBACK



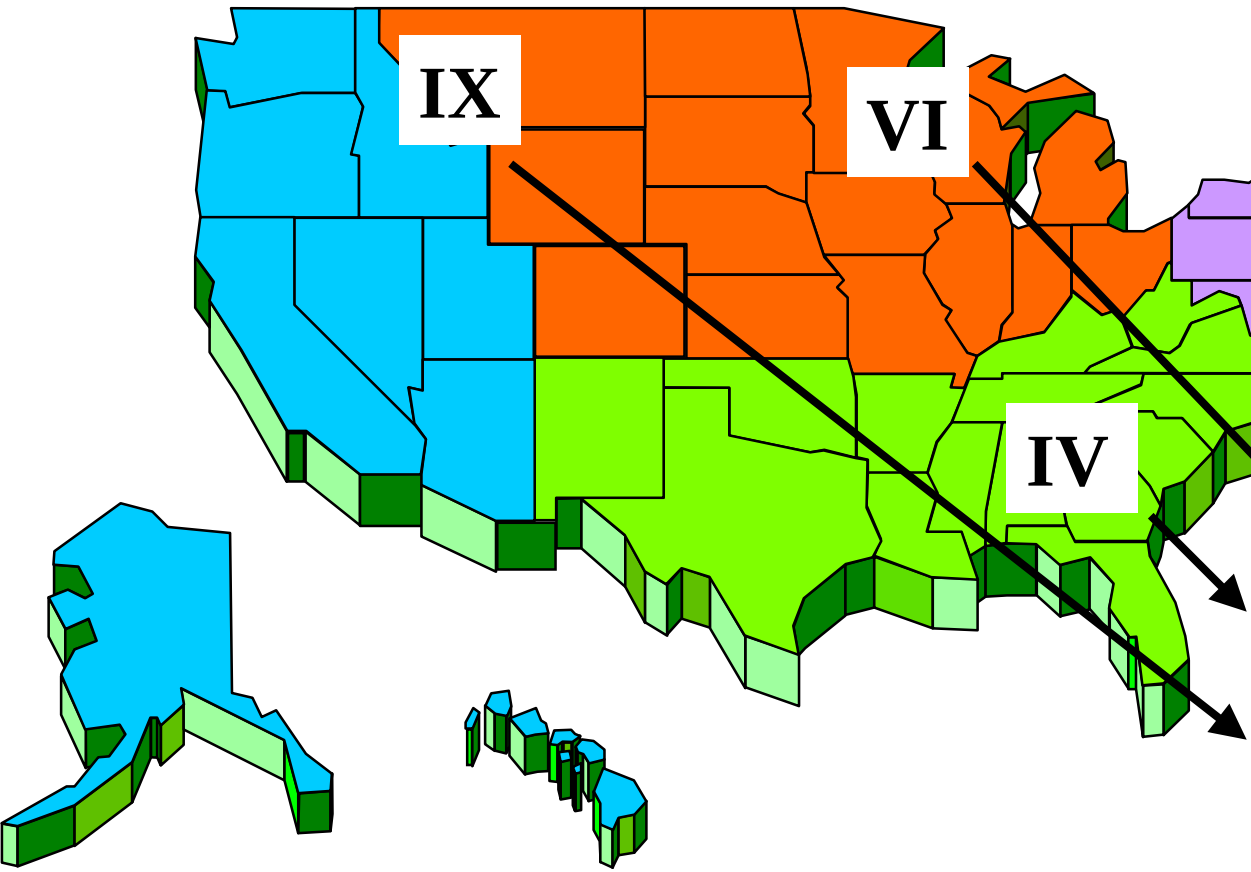
BURDEN

CONFUSION



FDA: Management, Analysis, and Action

Coordinating Center: Maintain uniformity and quality control; Materials development; Advisory Group



Recruit probability sample of facilities within each region - 50 per region; Data to Coord. Ctr; Grassroots voluntary reporting

Global Harmonization Task Force
Study Group 2

Canada 

European Union 

United States 

United Kingdom 

<u>22* Members</u>

10 Industry

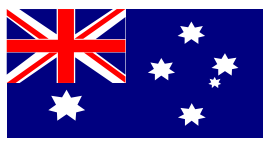
10 NCAs

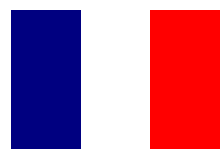
2 Other

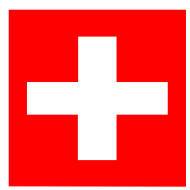
- EC
- ECRI

Japan 

 Germany

Australia 

 France

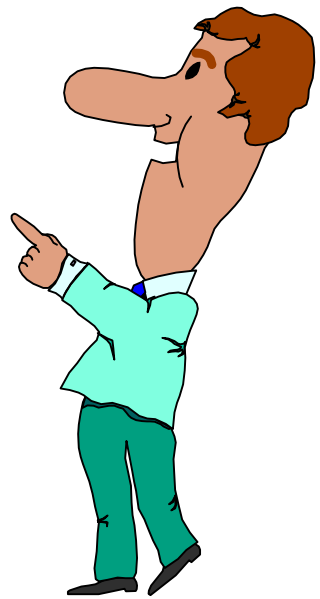
 Switzerland

 Belgium

SG2 Activity Highlights

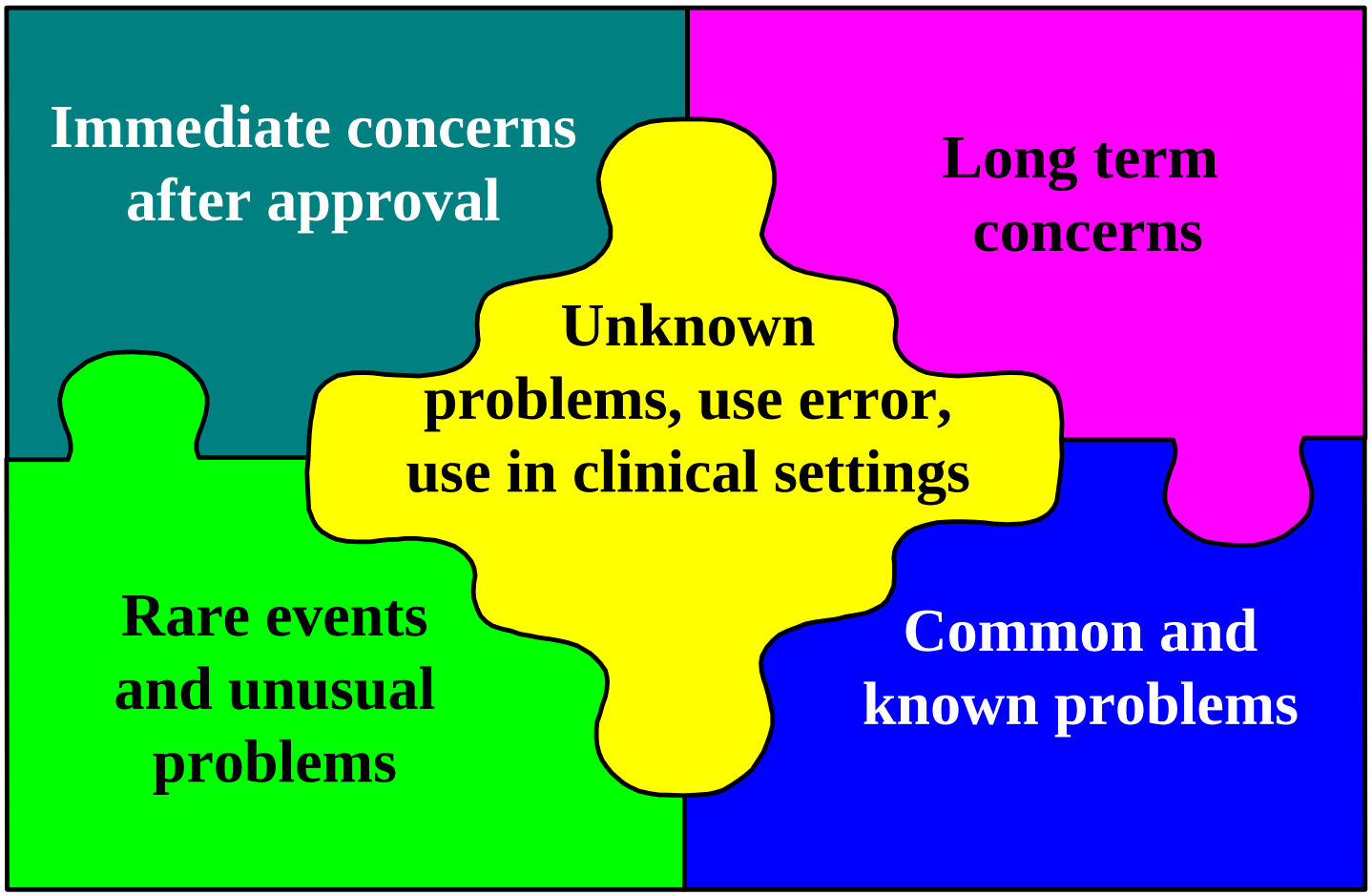
The NCAR/Vigilance Report Exchange Program-
A successful pilot project for AE exchange: going global

SG2 N21 Manufacturer Reporting Guidance-
Universal agreement on what is reported to NCA



Key Projects-
-N 32:Mfr. Universal Dataset
-N 33:Mfr. Report Timeframes
-N 36:Mfr. Trending of AEs
-N 31: Use Error Reporting

Integrating the Pieces of the Postmarket Puzzle



A Few Interesting Research Questions

- What are optimal strategies for postmarket monitoring of devices?
- For rare but known events, since MDR won't pick up modest excesses, what mechanisms can fill this gap?
- What are useful metrics for weighing risk vs. benefit for devices? How does this reflect changing knowledge over time?

Postmarket Study Authorities: Postmarket Surveillance (Section 522) and Postapproval (PMA)

- Two types of regulatory mechanisms
- Provide FDA the opportunity to ask key surveillance questions of “high risk” devices or where failure may cause death or serious injury
- Used with considerable caution

Postmarket Surveillance Study Design Approaches

- Detailed review of complaint history/literature
- Non-clinical testing of device
- Use of existing data sets, e.g., Medicare
- Telephone or mail follow up of patients
- Use of product registries
- Case control studies
- Randomized trials

Frustrations in the Postmarket Period

- Rapid evolution of technology make studies obsolete
- Lack of incentives for the industry
- Lack of interest in the clinical community
- Lack of clearly specified public health question

Vision for the Future

Developing a new system of reporting for a selected sample of well-trained and motivated hospitals; electronically based

Expand system to include all medical products

Expand access to different data sources, e.g., registries

Improved knowledge of medical products in clinical settings

Focus on lifecycle of the product (feedback to premarket)

Prevention of error, improved patient safety