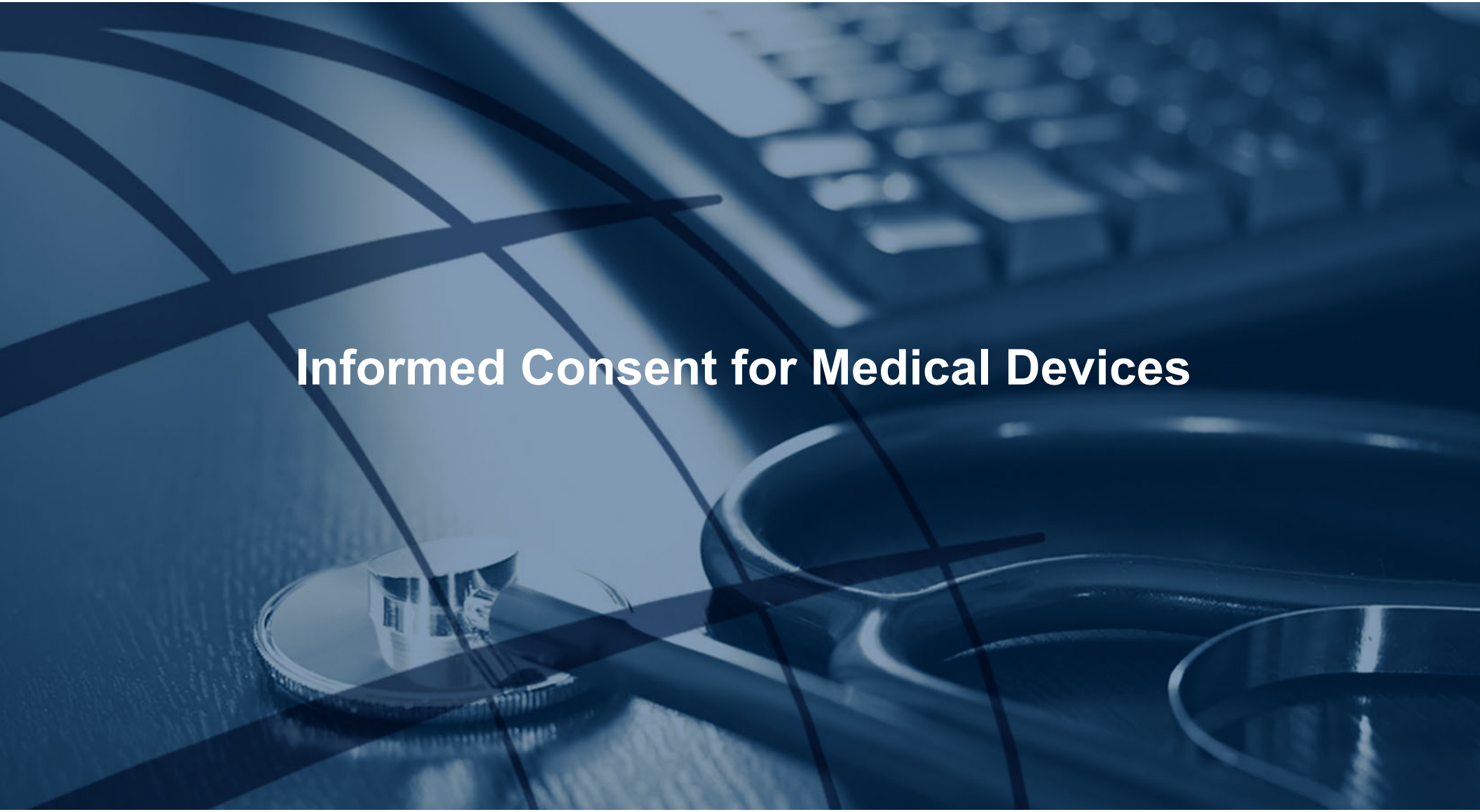

Informed Consent for Medical Devices

DEVICE EVENTS™

MASTERING MEDICAL DEVICE DATA

Madris Kinard, MBA

Founder and CEO, Device Events

FDA's Unique Device Identification (UDI) External Program Manager (former)

FDA's Adverse Events Subject Matter Expert for Devices and MAUDE (former)

Author, JAMA Internal Medicine invited commentary: Identification and Market Removal of Risky Medical Devices

Member, American Hospital Association's Learning UDI Community focused on encouraging hospitals to track devices with UDI

Member, UCSF Team for High-Value Care, Breast Implant Safety Alliance, Patient Safety Action Network, and the MDIC Science of Patient Input workgroup

www.linkedin.com/in/DeviceEvents

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Informed Consent for Clinical Trials is a little different than it is for devices already on the market.

When a device is already on the market, the UDI (like a UPC that is used to recall peanut butter) barcode should be provided for each device being implanted. If not all items are known in advance (such as surgical staples or clips), the patient should be informed they might be used as part of their surgery. Including the UDI (with lot number) in the Electronic Health Record can allow for better tracking and recalls.

Note: This is an opportunity for the provider and patient to discuss metal allergies, hypersensitivities, and autoimmune issues that may indicate, for example, that sutures would be less risky for surgery than clips or staples left behind.

There typically is no device label yet for a Clinical Trial, but if there is, provide it to the patient.

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Going Concern

Some devices are used **off-label**, and physicians need to be clear with a patient when that is the case. The study of off-label use of an existing marketed device may be the reason for the clinical trial.

The FDA receives some data from device registries, and sometimes the adverse events are for the primary device, but the sheath or implanted surgical clip may have caused or contributed to the issue. If those components or surgical devices are disclosed and the UDI is provided, the reports to the FDA will be more helpful.

Assume your trial will lead to a product that will be used long after the trial ends.

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Informed Consent

Informed Consent documentation should also provide the patient with where to turn if adverse events occur:

- **During the clinical trial**
- **After the clinical trial has ended**

If the trial has ended, let the patient know where to report adverse events. Ideally, this would be to the FDA since the device may have been cleared/approved to enter the market.

- **Note: If it is not immediately a problem after surgery, patients don't go back to the surgeon. They may tell their family doctor, rheumatologist or an endocrine specialist.**

Not all trials follow the patient long enough to identify all problems.

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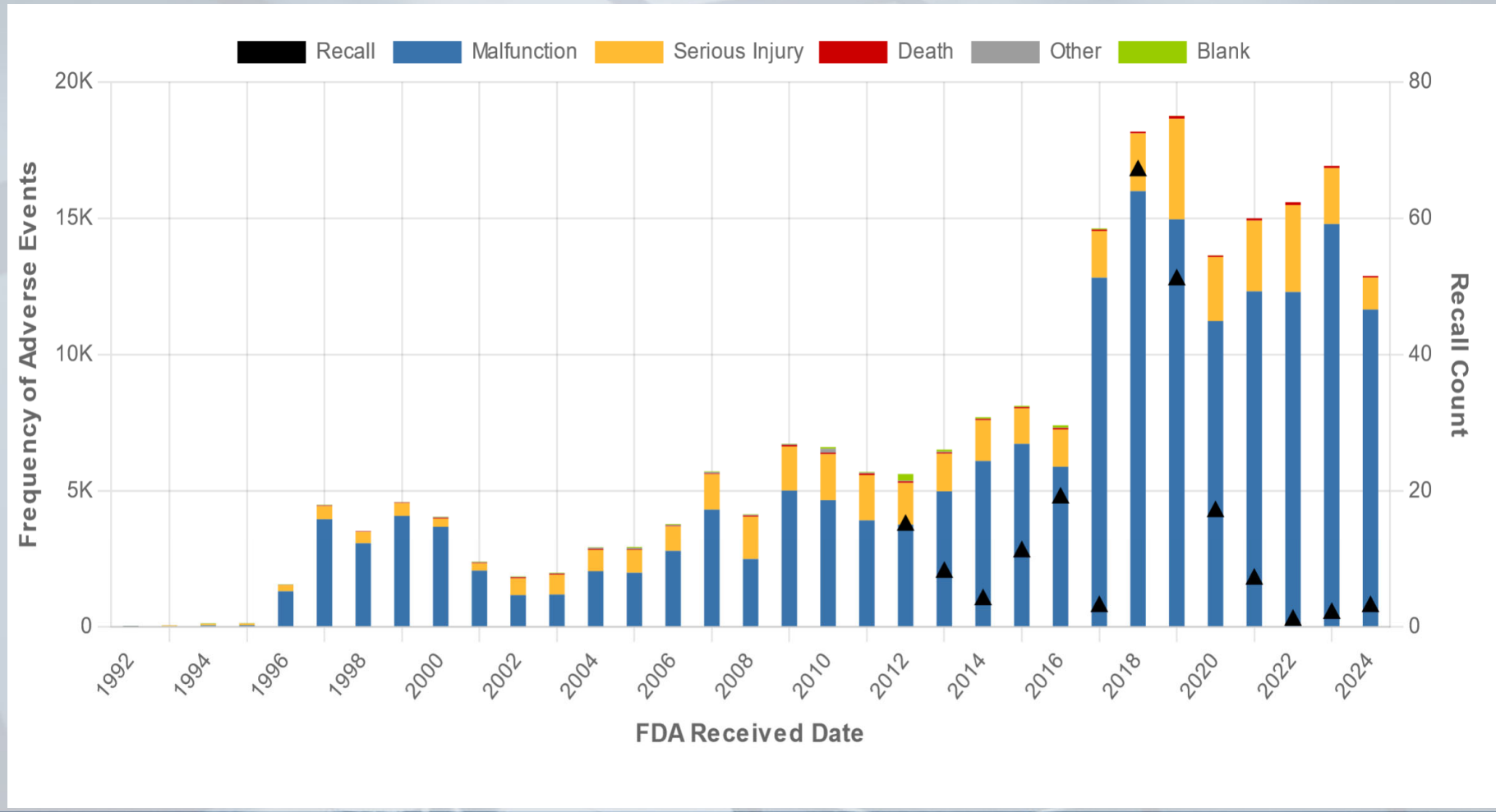
Adverse Events for Surgical Clips & Surgical Staples/Staplers Reported to the FDA



Devices used as part of a surgery can also cause issues, years later.

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Informed Consent

The FDA's MAUDE database houses adverse event reports (MDRs) for all types of devices.

At current count, there are over 19 million reports of serious injuries, deaths and malfunctions.

The Office of the Inspector General estimates that only 14% of adverse events get reported to the FDA. WHY?

Reports of adverse events only occur when there is a realization that a device may have been used and may have contributed.

What Needs to Happen Now to Improve Informed Consent and Address Going Concern?

1. The FDA needs to require that UDI collection and communication be included in Informed Consent.
2. The FDA needs to do a public UDI-awareness campaign for physicians, hospitals and patients to understand a UDI (the same way a UPC is used for consumer products).
3. The FDA needs to encourage physicians to communicate what is in the device, whether it is MRI-compatible, and what procedure might be needed if the implant fails.

The UDI is a tool…not a barrier.

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What Needs to Happen Now to Improve Informed Consent and Address Going Concern?

4. The FDA needs to require that informed consent provide information about follow-on care that might be needed when the trial ends, and whether the cost of that care will be covered by insurance or as part of the trial.

5. The trial needs to encourage patients to communicate with their regular care providers when the trial has ended. What are they permitted to share and when? Earlier is better.

Patients should be regarded as people who need to have continuing care even after the trial ends.

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Contact Information

Madris Kinard, MBA

Madris@DeviceEvents.com

240-424-8562

www.DeviceEvents.com

www.linkedin.com/in/DeviceEvents

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