How Can We Help Outpatient Adverse Event Communications?

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*Web*MD®

Current System of Adverse Reporting

- Manufacturer of product

- Patient initiated reporting through the FAERS

- Physician or Hospital reporting information

- Retail pharmacies

Changing Landscape

May be additional pressures on FDA to approve drugs faster:

- "While the administration pushes for less regulation and faster approvals, those decisions have consequences."
  - *Healthcare Finance May 2017*

- "Our analysis provides reassurance that the FDA continues to complete regulatory reviews more quickly than the EMA."
  - *NEJM April 2017*

- Could this impact adverse event reporting?
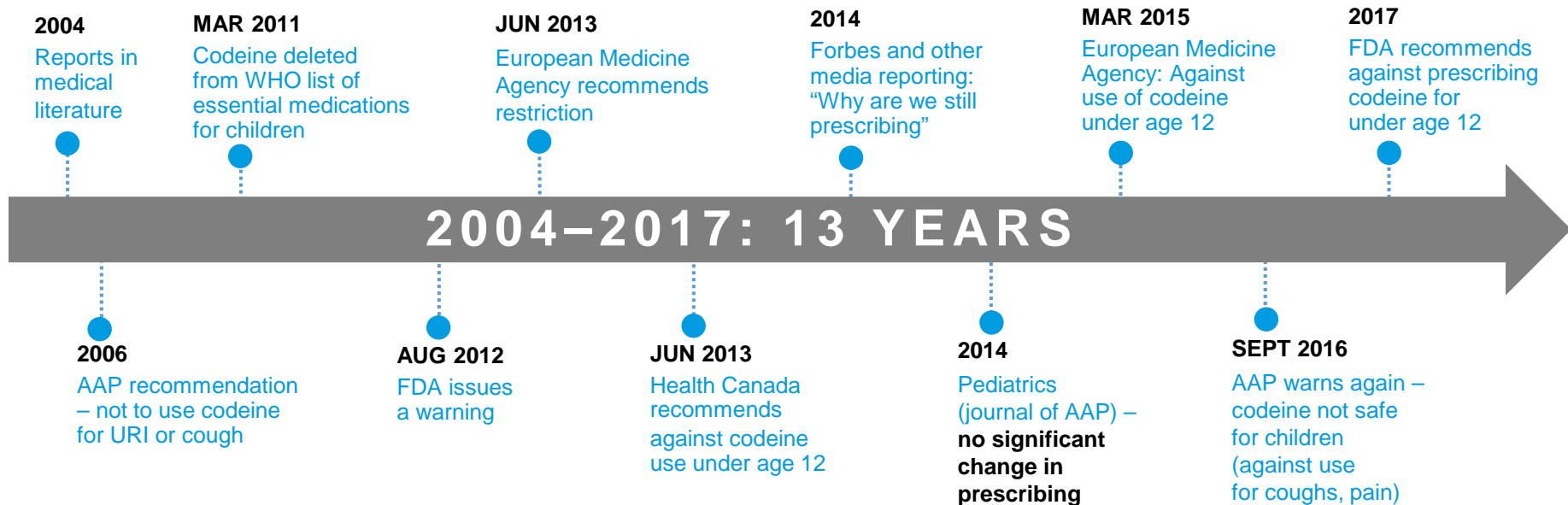
Limitations of AE Reporting and Action: Time Lag

2 main issues

- Time for reports to come in/analysis
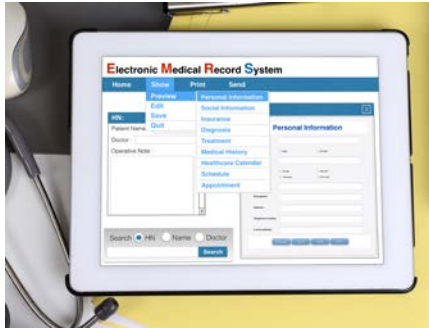
- Time to impact practice

Case: Codeine and Children

2004
Reports in medical literature

MAR 2011
Codeine deleted from WHO list of essential medications for children

JUN 2013
European Medicine Agency recommends restriction

2014
Forbes and other media reporting: "Why are we still prescribing"

MAR 2015
European Medicine Agency: Against use of codeine under age 12

2017
FDA recommends against prescribing codeine for under age 12

2004–2017: 13 YEARS

2006
AAP recommendation – not to use codeine for URI or cough

AUG 2012
FDA issues a warning

JUN 2013
Health Canada recommends against codeine use under age 12

2014
Pediatrics (journal of AAP) – **no significant change in prescribing**

SEPT 2016
AAP warns again – codeine not safe for children (against use for coughs, pain)

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Addressing Time Lag: Opportunities

Hospital EMRs
with tracking of code –
can we identify a pattern
and make MDs aware?

Urgent care clinics:
huge growth

Retail pharmacies/
pharmacists:
are they hearing
from patients?

Potential Consumer Solutions

Health websites:
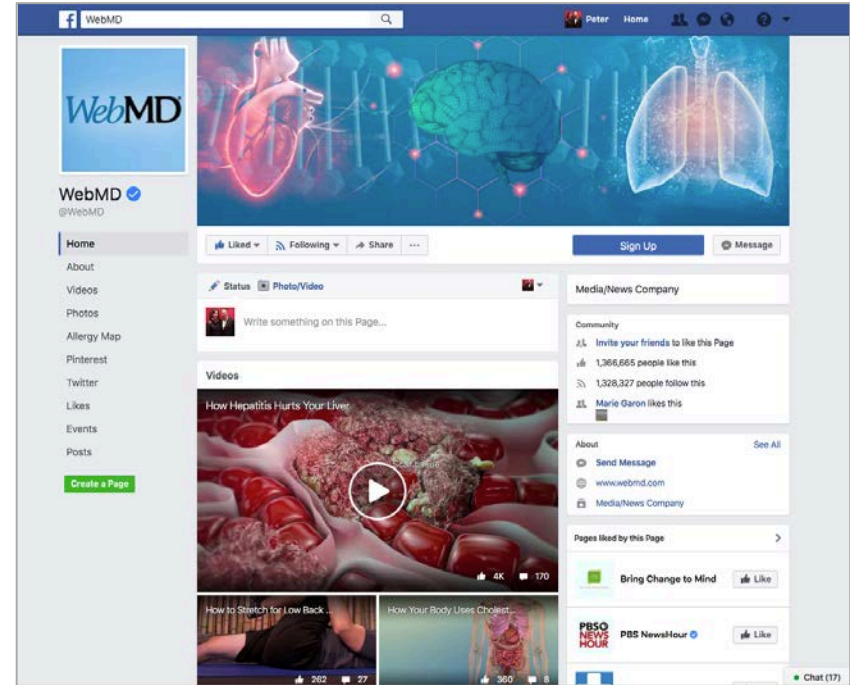often have a large user
base/know how to engage
patients

Government, hospital,
insurance, and
commercial websites
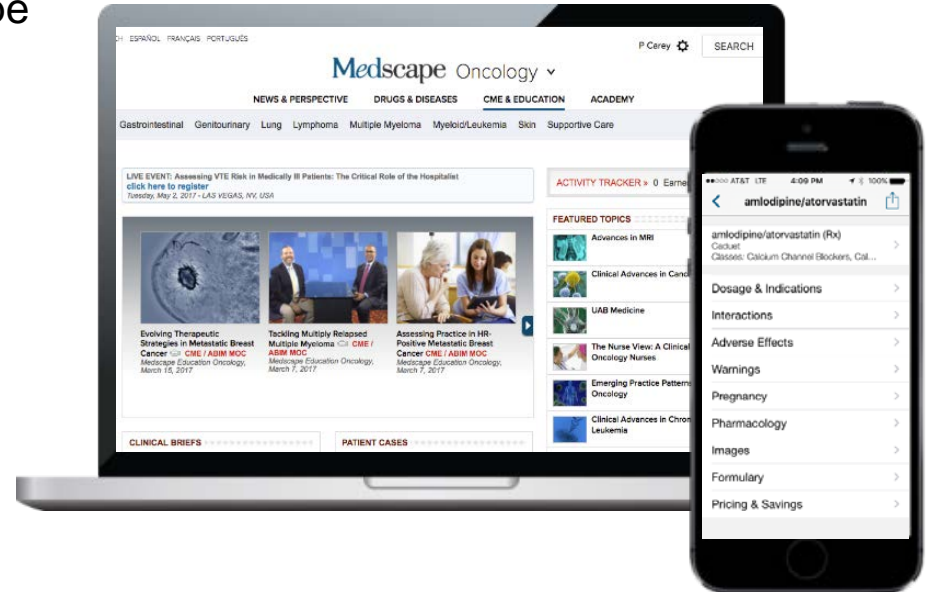

Going where
the patient is

Dispensing Information

- Key: Ability to get to the patient/person FAST with relevant information

- Using technology to collect data/dispense data e.g. apple research kit

- <u>Social Media:</u> Our FB post on antibiotics (partnership with FDA) garnered 1,800 shares, about 10x more than usual: reached greater than 200,000 people

- Other ideas e.g. Drug 'trends'

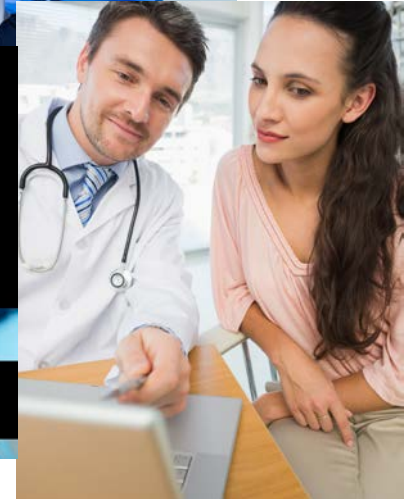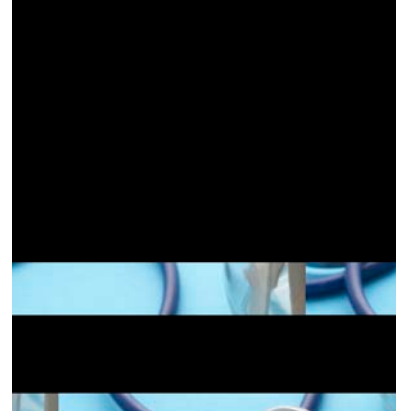# Potential Professional Opportunities

- Professional health websites e.g. Medscape

- Specific reporting interface to report in adverse events

- Could hospitals, or big physician groups, also use Medscape to dispense information: example 'drug trends'

Summary:

- Ultimate goal to communicate with the patient

- Make communications more efficient

- Potential solutions

  - Inward communications: Go where patients already are

  - Outward communications: Use innovative solutions to get key information to the public quickly

Safe Use Symposium:
A Focus on Reducing Preventable Harm from Drugs in the Outpatient Setting

Scott K. Winiecki, MD

Team Lead, Safe Use Initiative

Professional Affairs and Stakeholder Engagement Staff (PASES)

Center for Drug Evaluation and Research,

U.S. Food and Drug Administration

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David Classen

- "Temporary harm" is not temporary
  - Patients with an in hospital AE and at increased risk for AEs/continuing issues after discharge
- IT can provide a false sense of security
- The "safety nets" (EMR, pharmacy) can't be relied upon to catch errors

Tejal Gandhi

- Systemic approach to safety vs. "whack-a-mole"
- Recommendations for Achieving Total System Safety
  - Establish and sustain a culture of safety
  - Safety across the entire care continuum
  - Issues of physical and psychological harm to the workforce
- Translating safety measures from in- to out-patient, despite a lack of infrastructure

Heather Sundar

- Barriers to outcomes research
  - Difficulties with collaboration across organizations
  - Privacy issues
  - Access to timely and complete data
- Research is needed in
  - Polypharmacy
  - Medications covered by the medical benefit
  - Opioids
- "No one fix prevents medication errors"

Shonna Yin

- Health literacy as a state, not a trait
  - May change with time and/or situation
- Interventions to improve correct medication administration
  - plain language, pictograms, teach back, providing dosing tool
- Sharing and adoption of health literacy tools is challenging
- Dosing tool and size, mL only dosing can reduce dosing errors
- Active ingredient confusion

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Hansa Bhargava

- Time lag from finding/ publication to being put into practice

- Websites may be a resource to collect data on AEs and a resource to provide information to patients and providers

- Going where patients and providers are – if we are all on the web, make reporting via mobile devices easier.

Thank You

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