An Advocacy Journey: Passion, Persistence, Patience

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It's All About the Patient

- Goal: Engage in advocacy improve care for our patients
- Tendency to accept the "as is"
  - Side effect of disciplined approach to what we do as pharmacists and being in a highly regulated profession
  - We are always very busy

https://www.goodreads.com/quotes/tag/risk-taking, accessed 8/2/21

The Risk is Not Doing Anything

- **“...maybe sometimes it's riskier not to take a risk. Sometimes all you're guaranteeing is that things will stay the same” or worsen.**
- Barriers to practice represent opportunities for change
- Each person can make a difference

https://www.goodreads.com/quotes/tag/risk-taking, accessed 8/2/21

Monitoring the Legislative/Regulatory Landscape and providing input

- State Board of Pharmacy
- Department of Public Health
- The Joint Commission
- Center for Medicaid/Medicare Services
- FDA
- USP
- Updates from professional organizations

The Beginning: Tech-Check-Tech

The 13-Year Journey

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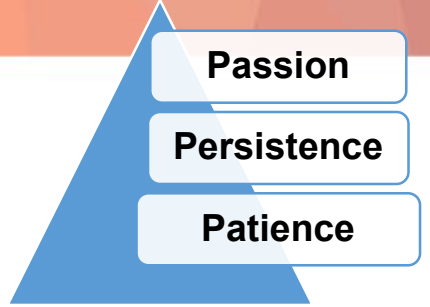
Tech-Check-Tech

Early 1990's, California State Board determines tech check tech is no longer allowed

- Early advocacy efforts at State Board meetings
- Listening and learning
  - What worked/what didn't
- Research Study I
  - *Accuracy of techs vs pharmacists checking cassettes, $p<0.05$*
- Continued objections

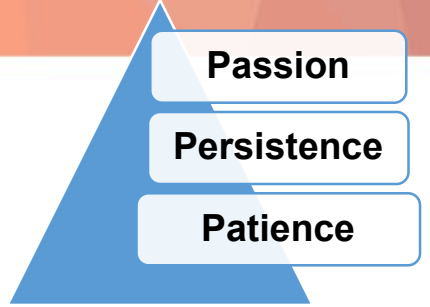
Tech-Check-Tech

- Research study II and patient safety stories
  - *Pharmacist impact on prescribing and administration errors*
- Drafting the language
  - Link to existing state board language
  - "Only inpatient hospital pharmacies as defined in 4029(a) that maintain a clinical pharmacy services program as described in 4052.1 *(clinical pharmacy services)* may have a technician checking technician program as described"
- Approval in 2007



Lessons Learned from Tech–Check-Tech

- Listen and learn about concerns and opposing opinions
  - Tech-check-Tech perceived to be a threat to pharmacists' jobs
- Determine shared goals around patient safety: Getting to win:win
- Share other state's experiences
- Engage like-minded leaders, professional organizations, schools of pharmacy



Lessons Learned from Tech–Check-Tech

- Leverage evidence: existing if available or propose study to demonstrate safety
  - Conducted studies with UCSF School of Pharmacy
- Don’t give up: Prevalent thinking, “it will never happen”
  - Develop relationships with State Board leadership and members
  - Strategic thinking: how to address concerns and limit scope of tech check to hospitals
  - Study II idea proposal vetted with State Board leadership

Joint Commission Proposed Standard

Prospective pharmacist review of orders not necessary once computerized physician order entry (CPOE) implemented (2002)

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Joint Commission Proposed Standard

- CPOE still under early development
- Evidence demonstrated electronic health records could not integrate patient-specific factors, e.g. renal function, age, other diseases/conditions, etc
- Pharmacists evaluate orders in the context of the WHOLE patient
- Expert panel convened by ASHP with TJC and pharmacy leaders

Joint Commission Proposed Standard

- Expert panel convened by ASHP with TJC and pharmacy leaders
- Submitted TJC Standards comments:
  - CPOE has been implemented in relatively few hospitals in a non-research, non-beta-test site capacity.
  - Implementation experience and outcomes from these hospitals have not been published in peer-reviewed journals.
  - AHRQ located published evidence of the effectiveness of CPOE with clinical decision support for only two hospitals, both of which were teaching hospitals. Report concluded that while CPOE holds promise, “the evidence is insufficient at this time to establish CPOE as a standard of care.”
  - Based on this report and the fact that CPOE technology and its implementation are largely still in evolution, it would appear that this standard as stated may be premature.

Senate Bill 1254
Medication histories for high-risk hospitalized patients

DEDICATED TO MY FATHER

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Rationale: MED WRECK

- Medication discrepancies occur in up to 70% of patients at hospital admission or discharge.
  Leapfrog Hospital Survey Fact Sheet 3/17
- Medication histories or lists are entered into electronic health records by a variety of individuals with varying knowledge about medications across different healthcare settings.

Rationale: MED WRECK

- Absence of designated “owner” to ensure accuracy of lists results in redundant work and rework by nurses, physicians and pharmacists
- Lack of defined process puts patient at risk for significant harm during hospitalization and at discharge
- Lists are used to create hospital medication orders and discharge prescriptions resulting in continuation of inaccurate and/or incorrect medications

Leveraging Evidence to Engage Stakeholders

2013-2016-Initiated topic of harm associated with inaccurate medication lists as a public health issue at California State Board of Pharmacy and California Hospital Association

Growing body of evidence showing increased accuracy when lists are obtained by pharmacy staff

CSMC study demonstrates 80% reduction in medication history errors and severity of errors when pharmacy staff obtain medication list. When not corrected, average of 3 inpatient errors/patient; 1.2 errors/pt are serious or life-threatening.

2017: Evidence-based infographics developed to provide education and gain support for problem and proposed solution

Up to 70% of Patients Have Errors on Their Medication Lists

Leveraging pharmacy staff prevents harm and increases clinician time for patient care functions

Problem

- 20% of admissions are medication-related[1]
- High risk patients have 8 errors on admission medication lists.[2]
- Only 5.3% of patients 65 year or older on ≥5 medications have accurate lists[3]
- One third of inpatient orders have errors and 85% originate from the medication history[4]
- Up to 59% of errors can cause harm[5]
- Up to 80% of patients have at least 1 medication error at discharge[6]

Solution

On admission, studies demonstrate increased accuracy of medication lists obtained by pharmacy staff vs usual care

- Accuracy rates: Nurses, 20%; Hospitalists, 50%; Technicians, 100% [7]
- Nurses 14% vs pharmacy technicians 94% ($p<0.0001$)[8]

At discharge, pharmacists identified errors in medication lists in 49% of patients and problems in an additional 16% vs usual care[9]

Business Case

Cost of Harm

- Cost of adverse drug event (ADE): $2,262- $5,790[7,10-13]
- Increased length of stay due to ADE: 3.1 days[13]
- Cost/readmission ~ $12,300-13,800[14]

Benefits

- 75% reduction in ADEs[7]
- 41 minutes of nursing time saved/patient[16]
- Cost-effective to utilize technicians for medication histories; $830,000[7]
- Patients have an accurate medication list upon discharge
- Reduced readmissions
- Enables clinicians to practice at the highest level of their license and training

Recommendation: For high-risk patients, pharmacy will ensure the accuracy of the medication list at admission and discharge

Professional Relationships Provide Opportunities

- ASHP Midyear 2017, professional colleague scheduled virtual introduction to California State Senator Jeffrey Stone, Pharm.D.
- December 19: Discussed concept of bill with Senator Stone
- Draft Senate bill due January 3
  - Senate bill with financial modeling based on published and state hospital data
- Conference calls with Senator's office and pharmacy colleagues to discuss strategies, potential barriers and their resolution

The Legislative Process: State Senate and Assembly Committees

- Personal stories
- Stakeholder Testimonies

SB1254 introduced February 2018

- First committee is critical
- Bill introduction and rationale
- Testimonies from stakeholders
- Unanimous approval

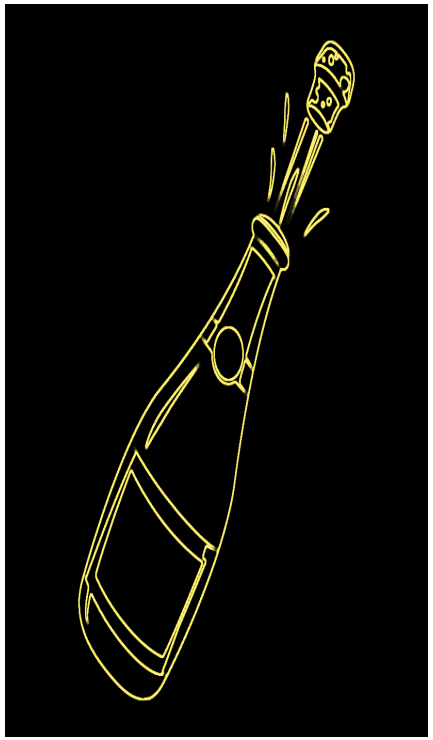
April 2018-August 2018:

- Senate and Assembly Committees, Appropriations, Floors,
- More testimonies

Bill passes unanimously at each step, sent for signature

September 19: Discussion with Governor's office

September 22, bill signed by Governor



Payer Policies

White bagging and Biosimilars

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Health Plan Policies: Risks to Patient with Cancer and Complex Diseases

Health plans have implemented policies that disrupt treatment for patients with cancer and complex diseases creating risks to patient safety and interfering with patients rights.

White Bagging

- Requirement that medications are obtained from outside sources without ability to verify drug product integrity, give drugs needed emergently and without the patient's knowledge.

Biosimilars

- Requirements that patients are switched to designated health plan preferred biologic drug during treatment. Hospitals and clinics must ensure health plan preferred biologic drugs are used – one biologic therapy could have up to 6 formulations of the same therapy for cancer patients creating risk of mix-ups and errors. Of note, there are 57 steps in checking chemotherapy.

The White Bag Problem

- Medications used to treat patients with cancer and complex diseases are no longer permitted to be acquired by hospitals and clinics that provide care for these patients
- Health plans require that medications come from designated pharmacies that send the medications to the hospitals and clinics
  - Source of medication and temperature stability cannot be verified
- Medications needed for urgent treatment are unavailable

The White Bag Problem

- Medications that require dose changes cannot be made resulting in delays in care
- Patients do not know that these medication primarily being given intravenously, and at times, by an injection, aren't being dispensed from the hospital or clinic where they receive care
- Medications need to be prescribed twice: once in the electronic health record and then another time to be sent to the outside pharmacy

REGULATORY CONFLICTS: PATIENT'S RIGHTS

Centers for Medicare & Medicaid Services Conditions of Participation

- 42 CFR §482.13(b)(2) TAG: A-0131: (2) The patient or his or her representatives (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, **being involved in care planning and treatment,** and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

REGULATORY CONFLICTS: PATIENT'S RIGHTS

The Joint Commission September 20, 2021 Revision for RI.01.02.01, EP 1

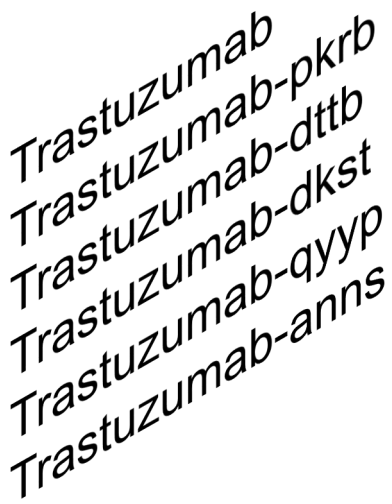
- Hospital – Rights and Responsibilities of the Individual: The hospital involves the patient in making **decisions about their care, treatment**, and services, including the right to have the patient's family and physician promptly notified of their admission to or discharge or transfer from the hospital.

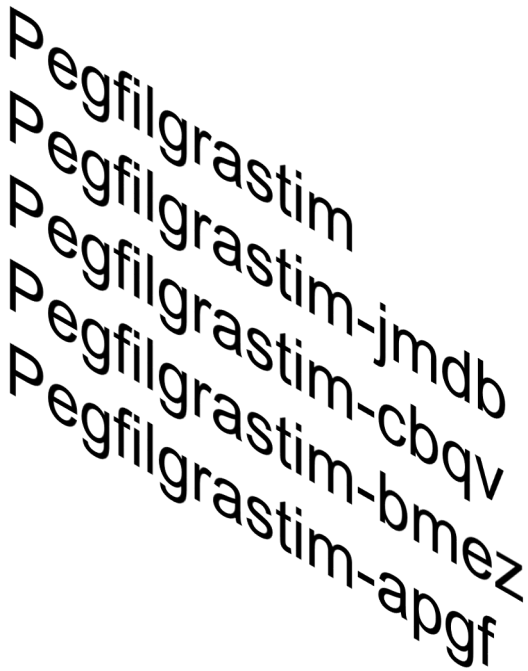
Biosimilars

- Biosimilars are biologic medications used to treat cancer and complex diseases which have “no clinically meaningful difference” from the reference (name brand) product in terms of safety and effectiveness
- Health plans are specifying which biologic or biosimilar products patients are to be administered to patients in hospitals and clinics
- The patient’s treatment is determined by the health plan not the clinician; cancer and infusions centers need to stock the health plan specified product.
- Disruption in therapy
- Delays in patient care
- Significant risk of mix-ups and errors

Biosimilars

Two biologics and their biosimilars used in cancer





Of note, proposed Senate Bill 1452 prohibits a health care service plan or health insurer from determining which manufacturer's biological products or their respective biosimilars are to be used when medically necessary biological products or their respective biosimilars are prescribed. ***This bill was developed in 2020 but was not introduced due to the onset of the COVID-19 pandemic***

Advocacy as a Journey

Big Picture	Evidence, Data, Stories	Relationships	Stakeholders	Respect and Knowledge
Monitor current healthcare trends Identify opportunities and barriers to advancing pharmacy practice	Gather evidence and develop subject matter expertise Bring data Share key examples	Develop relationships with decision-makers and like-minded professionals	Engage stakeholders: Local, State and National Professional Organizations, Clinicians, Executives	Demonstrate respect Under context, perspective of audience Bring forth your expertise and create credibility

Advocacy as a Journey

Timing

Persistence

Patience

Life begins at the end of your comfort zone.
Neale Donald Walsch

Appendix

Evidence

- Up to 70% of patients have errors on their medication lists when they are admitted to hospitals[1]
- Only 5.3% of patients 65 years and older on 5+ medications have accurate lists[2]
- If not corrected, discrepancies/errors continue during an inpatient admission and at discharge
  - Study of high-risk patients identified eight errors per admission med list[3]
  - These errors resulted in an average of three errors per patient when they were hospitalized[3]
- One-third of inpatient orders have errors and 85% of medication errors originate from the medication history[4]
- If the medication lists are not accurate, the inpatient orders will be inaccurate

New Legislation

- New section added to California Business and Professions Code, 107.1 establishes pharmacist's responsibility in acute care hospitals for obtaining an accurate list of the patient's current medications on admission, or promptly thereafter.
- In hospitals, the pharmacist is responsible for obtaining an accurate medication profile for high-risk patients upon admission.
- This function can be completed by technicians and interns who have successfully completed training and proctoring by pharmacists and where a quality assurance program is used to monitor competency
- Passed into law September 22, 2018
- Enforced January 1, 2019

https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180SB1254 accessed 1/3/2019

White Bagging

Drug integrity safeguards are bypassed: controlled storage; unclear medication source;

~70%* of whitebagged medications are for intravenous infusions requiring sterile compounding

Delays can be life-threatening: drugs and doses just-in-time modifications for patient-specific conditions

Delays in discharge and readmission risk

Lack of financial patient assistance

Disruption of safety of medication orders

Drug supply chain disruption: Patient-specific supplies, drug recall management

Disruption of dose modification based on patient's cancer/disease