Drug Safety - Catch 22

"Complications due to medications is the 2nd Preventable Cause of Death in Hospitals"

Dr. Eyal Zimlichman, Tel Ha'shomer Hospital, Israel.

"If 77% of drug admission complications are preventable, why is it still the 4th cause of death in the west?"

Dr. Irene Fermont, IsOP Israel

At the multidisciplinary symposium "60 degree of Drug Safety" on June 3-4, 2019, experts from the US, Canada, UK, France and Israel represented academia, hospitals, pharmacists, big Pharma, startups,... They discussed the challenges, presented their research, solutions & pilots preventing complications, especially when the hospital and the families are involved.

- In UK 237 million drug errors annually
- In **US hundreds of thousands deaths** from drug errors.
- The global cost of inadequate communication between the health system and the individual patient costs 290 Billion US\$
- Only 20% of all cases are reported, i.e. 80% of drug errors are UNKNOWN!

The Main Reasons for Drug Admission Errors:

- A prescription's rocky road to the patient changes in prescriptions when transferring from one institution to another, duplicate /contradicting prescriptions from multiple doctors, errors in prescription spelling, reading and copying.
- **The human factor** considering staff fatigue and weariness, lack of knowledge or training and similarity in drug names and packaging.
- The plethora of drugs (polypharmacy) and new generations of drugs, such as Anti-coagulants, opiates and biologic drugs, increase risks of complications.

ADE (Adverse drug Events) occur at all ages, not just the elderly. Children and infants are victims as well.

Life & death at the hands of the patient & family.

1 of 1000 prescriptions in hospitals will have a decimal point error, i.e. 10 to 100 times error!

<u>Tal Givoli</u>, CEO of **Medivizor**, shared with tears in his eyes how his daughter became a victim of one of the most common errors in hospitals. During her hospitalization she suffered splitting headaches with no apparent reason. Givoli noticed one of the instruments indicated she was receiving ten times the amount of prescribed epinephrine. How did he know? His own startup has an application that "translates" prescriptions to layman terms. Hence, it give users more knowledge & control. It enabled him to detect this Adverse Drug Event and alerted the staff, thus preventing further damage. Unfortunately, in most cases parents aren't there or don't have the

know how to save their children. Such as the case of an infant that had a cardiac arrest and CPR attempts failed. The inquiry found that two hours earlier a nurse gave him ten times the prescribed dosage of Digoxin. Instead of 0.01mg, she administered 0.1mg.

Prof. Gidi Koren, Maccabi Institute of Research and Innovation, reviewed researches & explored the severity of the issue. His findings show 25% of medical staff calculations were wrong — of which 8% stemmed from the decimal point (ten\hundred times the dosage). Medical schools don't teach how to calculate 0.01 milligram to a patient's kilogram. ADE is especially critical when administering drugs to infants with low body mass. Counter intuitively, most of the errors happen to senior staff who have less active practice in drug administration calculations. Additionally, most recorded ADEs happen at night between 4:00AM & 8:00AM, weekends and by interns.

The Solution: Empowering the gatekeepers

- 1. Technology and AI developing automated tools to identify ADEs including erroneous prescriptions, dosage errors, duplicate /contradicting prescriptions and admissions, allergies, etc. the Israeli Start-up MedAware implemented AI and in a Harvard research was able to identify 80% prescription errors. Thus assisting patients and medical staff. Prof. Ronen Loebstien from Tel Ha'Shomer hospital introduced a study that mapped out the challenges and opportunities in using computerized systems to alert and avert prescription errors. The main challenge in existing systems is the overflow of false positive alarms, generating alert fatigue within the staff. Machine Learning can reduce false positive alerts and increase the real alerts, reducing staff's alert fatigue and enhancing concentration when an alert goes off and a real emergency occurs. Having said that, the integration between human and machine is of outmost importance because each patient is medically unique, so the medical staff can benefit from more valuable input.
- 2. The patient as the ultimate gatekeeper. Empowering the patient and the family. Experts repeated the importance of the patient's gatekeeper role and the patient's responsibility to know and check what is being administered, for what, and the dosage at every juncture. Constructive interaction with medical staff is paramount. Start-ups and campaigns encouraging the patient to be more active, ask and inquire about the prescribed drugs, inquire about side effects and understand as much as possible the compound of active ingredients are promoted by the FDA, see: talkbeforeyoutake.org/ an FDA enterprise that gives the public tools to understand and be more informative before taking any drug related decision. Medivizor enables patients and families to locate the best doctors and treatments for 15 common diseases and offers an in-depth description of each one. According to Tal Givoli, Medivizor's co-founder, "it takes us two months to develop a program for any disease."
- 3. Combining staff awareness and integration of digital tools. Prof. Ron Litman, FDA Advisory committee, and director of ISMP— the largest drug safety institution in the world, demonstrated how ISMP tool assists hospitals assessing the effectiveness of an ongoing treatment and the administration process. The tool is free of charge for hospitals and Therapeutic Institutions and integrates different interfaces, including patient participation and a short protocol proven to assist in ADE aversion.

- 4. **Pharmacists** are a resource and an important checkpoint in the prescription drug supply chain. Sima Livni, a pharmacist from the Drug Consulting Center gave an example of a 70-year-old was treated with three different drugs sedatives, anti-depressants in addition to anti-psychotic treatment. When Livni met the patient, his depression had matured into full despair after being recently diagnosed with Parkinson. She noted some of his treatment side effects to include 'Parkinsonism' and sent the patient back to his physician recommending reducing the dosage of the aggressive psychiatry treatment before fully accepting the Parkinson diagnosis. The Dr. changes the prescription "Parkinson can tip anyone in despair, even individuals who don't suffer from depression." While there is a shortage of doctors and nurses in Israel, there is no shortage of pharmacists. They can be trained for consulting and monitoring prescriptions. According Prof. Ron Litman American insurance companies avoid claims reduce their costs by using consultants and agencies periodically check on patients at home, to prevent complications. Dr. Alina Amitai, President PSI, Meir Medical Center, presented a similar pilot by the Pharmaceutical Society of Israel, ISOP and Super-Pharm pharmacy chain.
- 5. Supervision over production, packaging and administrating drugs, removal from hospital wards and discontinuation. In Israel, like the rest of the world, regulations were implemented to stop administrating opiates to elderly for chronic pain, as they are ineffective, create complications and addictions. The US and Canada are currently steering towards medical cannabis and alternative approaches.
- 6. Accountable Empathy Breaking the CODE of SILENCE side by side with empathy to the PATIENTS & HEALTHCARE STAFF.

CATCH 22

"If an ERROR occurred, but NOT DISCLOSED in the medical record - everything appears o.k, but the patient deteriorates, and the following physician does NOT know why?"

Bottom line, all instruments and models, depend on teams willingness to report errors. Dr. Zvi Herschman, Founding Member, ISOP Israel, Toxicology Consultant in New York City, stated that: "As long as medical files can be revised, without documentation of the revisions - nothing will change. Accordingly, Families should have access to the original file, and not just the final version. Without this access, there is a potential cover up. This is a Catch 22."

"Some Physicians, nurses,... who erred may become secondary victims. This trauma combined with the inability to talk about it, hurts the care giver, damages its competence and it impacts the entire system" said Dana Arad from Israel's Ministry of Health,

MOH.

The MOH, Ofek foundation & Inbal Medical Insurance are forging a methodology to encourage medical teams to report errors in order to learn and improve. Special workshops enable affected patients\ families to share their story with medical teams in hospitals and nursing schools. Initial findings show that the workshops increase teams willingness to report errors from 30% to 50%. Dana Arad adds: "In most cases

physicians don't tell patients about their mistakes, out of shame or guilt. This creates physician aversion & loss of trust by the patient. The helpless patient continues to receive treatment from the caregiver that caused damage and the caregiver has no one to share the burden with."

"To make a mistake is human, repeating it is criminal" - Seneca, 4BC- 65AD.

<u>Dr. Gil Mileikowsky</u> President and Founder of the "Alliance for Patient Safety" USA, and "Alliance for Patient Safety" IL, strives to save patients lives and physicians careers. He says that: "The problem lies in the entire health system, as there is **NO credible & reliable quality control of delivery of care**, including in Israel. The MOH funds the entire system, it pays the insurance companies, hospitals, physicians, pharmacists, labs.... pays the compensations in law suits and is supposed to monitor itself. This is absurd. No system can be expected to perform and check itself objectively".

The Code of Silence: "46% do not report on errors" in the US according to the Institute of Medicine, IOM.

<u>Dr. Gil Mileikowsky</u> revealed the existence of an intriguing department in US Hospitals, the "Performance improvement department". Its role is to prevent leakage of information not only out of the hospital, but also within it. If a serious mistakes happens, particularly if it may lead to a law suit, the patient's medical record is immediately taken over by this department, into a room with a coded locked door like a safe. The entire team that witnessed the incident is instructed NOT to talk about it with ANYONE, except the hospital's lawyers and the insurance company.

One of the challenges, is finding physicians who will testify on behalf of the patient in court. Those who dare pay a very high price from alienation up to career destruction. In Oregon, 20% of physicians committed suicide when their license as suspended see: (JAMA).

The Devils' Arithmetic:

More treatments lead to higher hospitals' revenues. So, is it the hospital interest to minimize complications or maximize it?. When a physician at Soroka hospital discovered a way to decrease patients' infections, the hospital complained their income decreased. Redding, California, became a leader in bypass operations in the US, because 83% of the operations performed on HEALTHY people with NO heart disease.

The Rand Corporation found out that: "All adults in US are at risk for receiving poor health care, no matter where they live, why, where and from whom they seek care, or what their race, gender or financial status". "How is it possible?" asks Dr. Mileikowsky.

There are 3 economical systems in the US health care:

1. In the capitalist system, i.e. the "Fee for Service", Private care, patients are OVERTREATED.

Since wealthy patients and their insurance companies can pay, they receive maximum treatments and tests regardless of their necessity.

- 2. In the **socialistic system patients are UNDER-TREATED** because the HMO gets a limited budget per patient /year, regardless the treatments required. So, the financial incentive is to perform the minimum care possible in order to preserve the funds to be divided among shareholders, i.e. management, physicians, nurses...
- 3. In the **Public system, i.e.** "**Single Payer**", patients quality of care is **RANDOM**. Funded by Federal government, States, Counties, Cities,... Some of the Leading Medical Schools operate in such facilities, so the quality of the care provided can range from the best known experts to inexperienced interns.

"There are 2 other preconceived ideas about the health system:

- 1.Allegedly, the system is afraid of malpractice lawsuits and is doing everything possible to decrease errors and complications. Unfortunately it is not so, as the Quality of Care does NOT improve.
- 2. Malpractice law suits are increasing significantly the healthcare budget. In the USA awards from these law suits are only \$5 Billion, while the Health care Budget is close to 4 Trillion \$!"

Speakers list here

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