





Improving Drug Diversion Detection and Prevention in Healthcare - An NIH National Study

Webinar for International Health Facility Diversion Association (IHFDA)

Tom Knight

June 18, 2019







Disclosure of Relevant Financial Relationships

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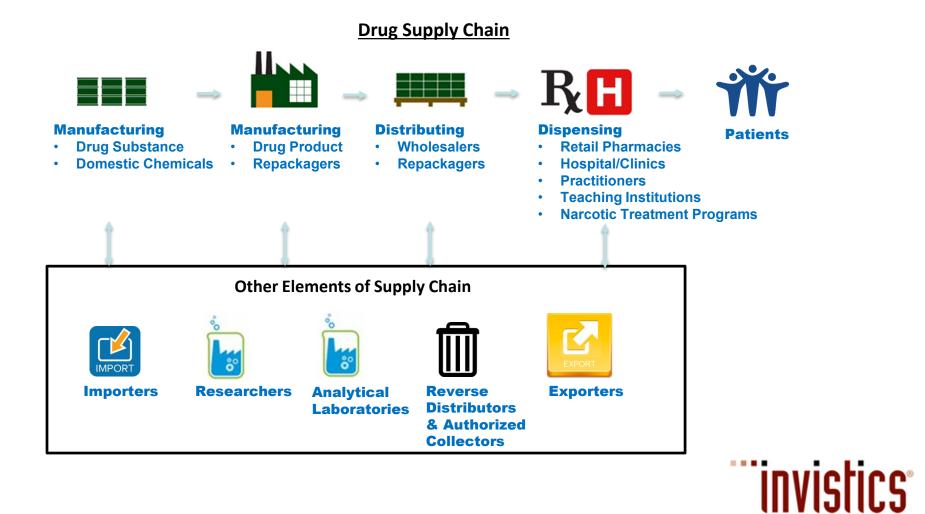
The presenter, Tom Knight, is the Principle Investigator (PI) leading this research at seven health systems across the United States, and owns stock in Invistics Corporation, the small business that received this NIH Award.

Disclosure of Off-Label and/or Investigative Uses

Tom Knight will not discuss off label use and/or investigational use in this presentation.



Pharmaceutical Supply Chain Experience



Agenda

- Introductions
- Diversion by Healthcare Workers
 - Why it Matters
 - Challenges with Current Methods
- NIH Study: Improving Drug Diversion Detection
 - NIH Study of Improved Methods
 - Results to Date
 - Next Steps
- Questions & Answers



How Prevalent is Drug Diversion in Healthcare?

"Rates of substance abuse and dependence are similar to those of the general population"

- 6-8% of Physicians, with higher rates for Anesthesiologists, e.g., 9.8% of Nurse Anesthetists.
- 9% of Pharmacists
- 4.7-8.8% of Registered Nurses

So for a typical, mid-size, 500 bed hospital, expect roughly <u>25-75 people</u> to be diverting at any one time:

- 6-10 physicians, anesthesiologists or CRNAs,
- 4-5 pharmacists, and
- 15-60 nurses

Sources: Baldisseri, "The Impaired Healthcare Provider" American Nurses Association (ANA) & the National Council of State Boards of Nursing (NCSBN)

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- 4-5 pharmacists, and
- 15-60 nurses

Yet most diversion is not detected, investigated, or reported

- 84% of hospitals investigated <10 cases last year
- 65% of hospitals investigated <5 cases last year

Most Diversion

Goes Undetected...

Until Injury or Damage Occurs

Sources: Baldisseri, "The Impaired Healthcare Provider" American Nurses Association (ANA) National Council of State Boards of Nursing (NCSBN)



Why We Must Improve Diversion Detection

Improve Patient Safety

- Impaired clinicians can injure patients
- Tampering causes patient infections

Protect Coworkers

• Detect diversion and abuse sooner, before addiction spirals out of control

Protect Community

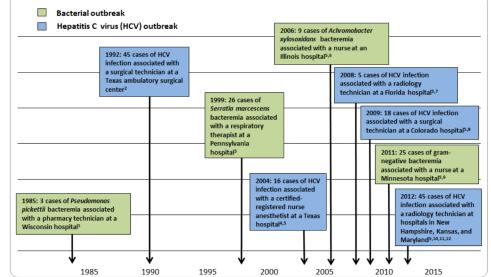
 Prevent addition and overdose deaths when stolen drugs are resold in community

Avoid Financial Fallout & Loss of Reputation

- Fines, e.g., \$4.3 million DEA fine
- Lawsuits from injured patients
- Damaging news coverage

Source: Invistics, as part of NIH Award Number 1R44DA044083-01, compiled from:

- Centers for Disease Control
- Inciardi, et al., The "Black Box" of Prescription Drug Diversion. J Addict Dis.
- 100+ articles in local newspapers and/or video segments on local TV News





Diversion Hurts Reputations and Community Trust

Tonight on your Local News? Headline in Morning Paper? "Hepatitis C cases identified at [Local] Hospital after nurse pleads guilty to stealing patients' hydromorphone and morphine"

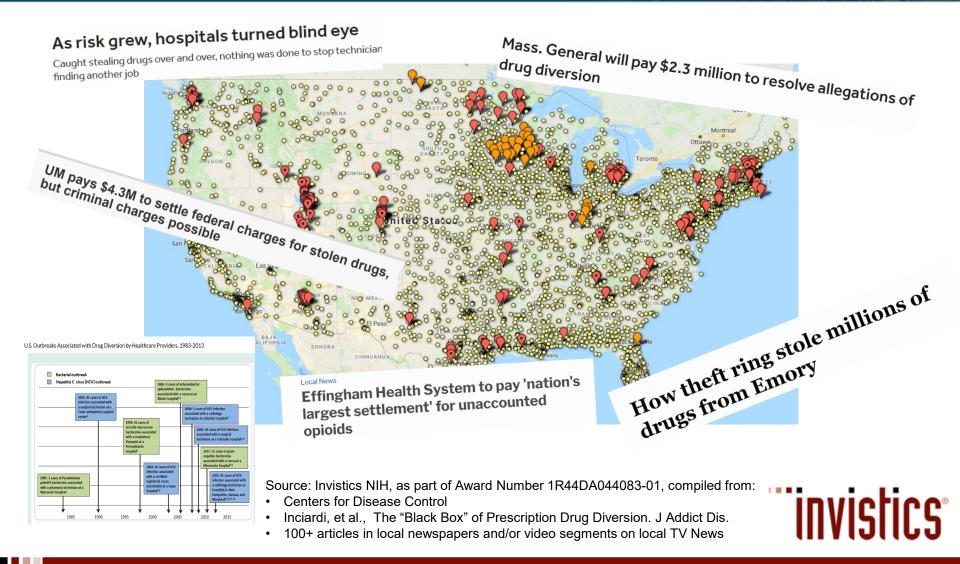


Dr. Angela Dunn of CDC speaks with reporters about an outbreak of hepatitis C at [local hospital].

Source: CDC and Standard-Examiner



Recent Hospital Drug Diversion Cases Please Visit <u>HealthCareDiversion.org</u>



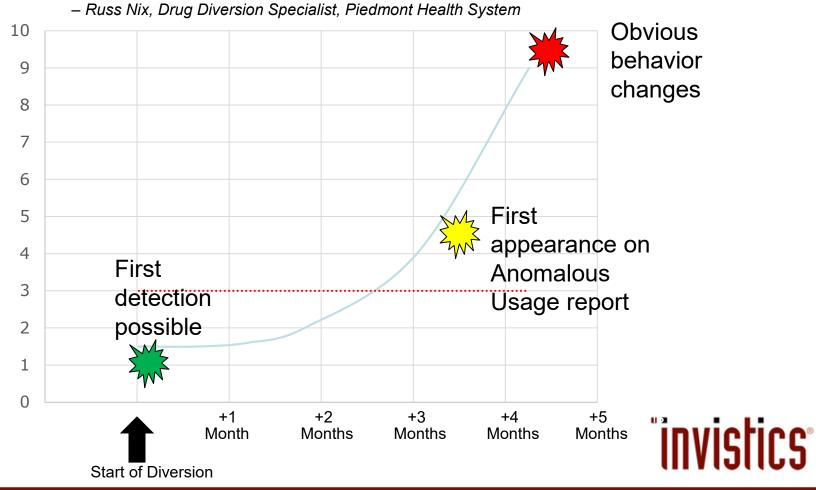
Current Diversion Detection Technologies

- Lock-up drugs in Automated Dispensing Cabinets (ADCs)
- React to tips, incidents, or monthly "anomalous usage" reports
- Dedicate person(s) to conduct manual investigations
- Investigations require painful reconciliation of ADC vs. Electronic Medical Records (EMR)



The Behavior Pattern of Diversion: Detecting earlier, before patient harm or addiction tolerance

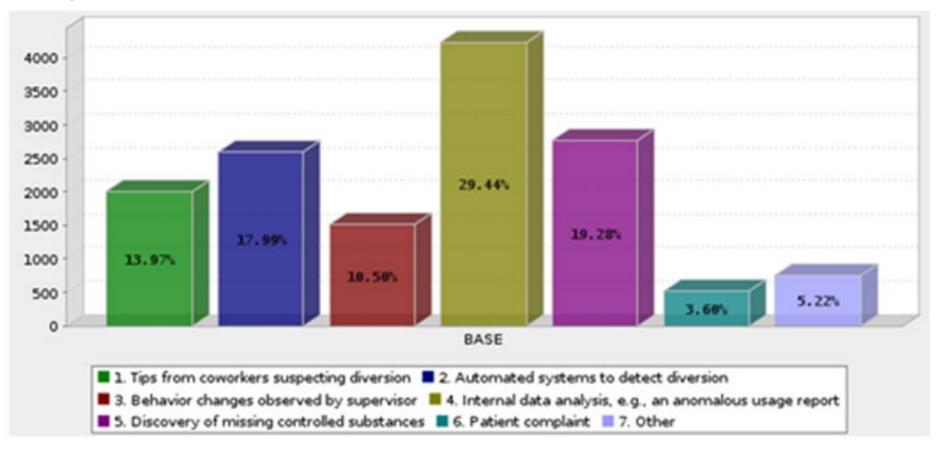
"The biggest liability in healthcare diversion is the time between the start of diversion and the discovery of that diversion...because that is when your patients and institution are most at risk"



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Currently, a majority of drug diversion in US Hospitals is detected reactively using "low-tech" methods

Q11. Within your organization approximately what percentage of drug diversion cases are initially identified via the following? Please allocate 100 points:





An investigation takes on average of 7.8 hours to complete

Investigations occur less frequently than needed

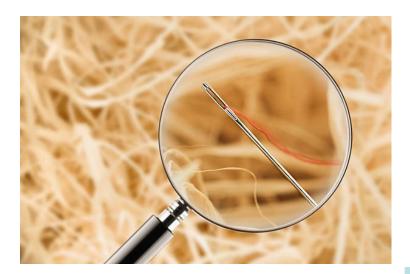
- 84% of hospitals investigated <10 cases last year.
- 65% of hospitals investigated <5 Investigations
- Even though a typical hospital would expect 25-75 people to be diverting

A majority of investigations do not confirm diversion





Problems with Current/Competing Technology Don't Waste Time Looking for a Needle in a Haystack



"70-80% of our alerts are false positives, which is a tremendous resource problem for us"
Pharmacy Director discussing innovation challenges in this field

Ineffective

- Fails to detect most diversion ("false negatives")
- Most alerts are false alarms ("false positives")
 => Alert Fatigue, especially for nursing & pharmacy
- Typically ignores:
 - Data available outside Automated Dispensing Cabinets (ADCs), like Pain Scales in EMR
 - Anesthesia
 - High-value medications that are not narcotics

Inefficient

- Slow to detect
 - Lack of real-time drug monitoring
 - Anomalous Usage reports are 30 days behind
- Time-consuming to Investigate
 - Investigations are time-consuming, 8-10 hours



Ignore the problem?

Hire more investigators?

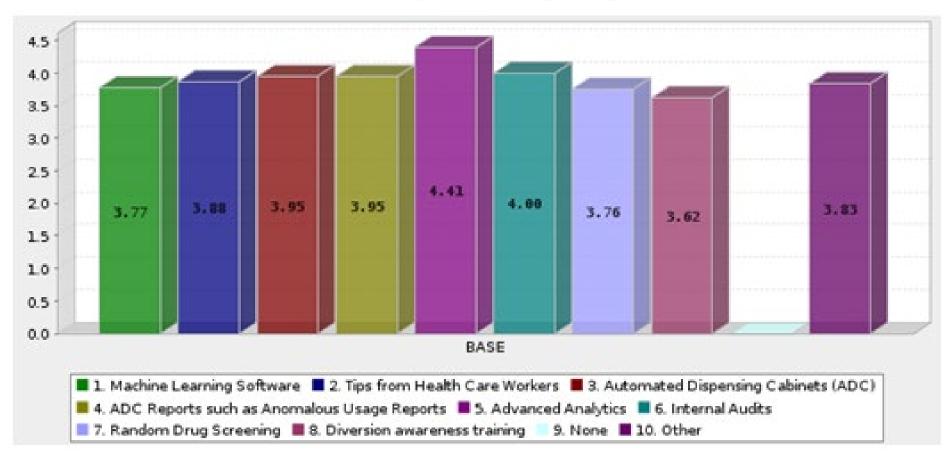
Look for a better way?



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Advanced Analytics was rated by HCWs as the most effective way to decrease drug diversion

Q10. Using the scale from 1 to 5, where 1 equals not at all effective and 5 equals very effective, please rate the overall effectiveness of each item in the identification and/or preventing drug diversion.



In Summary: We Have a Problem

- Numerous surveys, the <u>American Nurses Association</u> (ANA) & the <u>National</u> <u>Council of State Boards of Nursing</u> (NCSBN) say approximately 10% of health care workers are dependent on drugs, consistent with U.S. population.
- Hospitals agree:
 - Diversion is occurring universally
 - Most goes undetected
 - Diversion that is detected is usually too late, after:
 - deterioration in clinical performance
 - after most of the damage to the Health Care Worker, Patient, and Hospital is already done.
- Current methods for detection are both ineffective and inefficient,
 - 84% of hospitals investigate <10 cases annually</p>
 - Even though a typical hospital would expect <u>25-75 people</u> to be diverting
- Hospitals see Advanced Analytics would be more effective and efficient





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Overview of NIH Study



National Institute on Drug Abuse

- 30 Month Study
- at 7 Hospitals
- Diversion Detection using Advanced Analytics & Machine Learning



National Science Foundation WHERE DISCOVERIES BEGIN

UNITED STATES PATENT AND TRADEMARK OFFICE



 Expanding on research with MIT & U.S. Patent 7499766



Support Letters from 129 Hospitals, plus Law Enforcement, Schools of Pharmacy, etc.







Our NIH Fast-Track Study: Three Phases

- Phase 1
 - One Hospital
- Phase 2
 - Original scope: 6 Hospitals
 - Funding expanded, twice: 28 hospitals to date
- Phase 3
 - Roll-out
 - In Collaboration with State & Federal Stakeholders
 - Building a national network of healthcare diversion incidents, to prevent future diversion and its victims
 - Expanding beyond hospitals to all healthcare facilities

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Focus of NIH Study for Diversion Detection



- Proactive, real-time monitoring
- Transaction integration and reconciliation of
 - all healthcare workers, and
 - all drugs at risk of diversion
 - across multiple systems and departments
- Advanced analytics and machine learning
- "Alerts" signaling suspicious or noncompliant behaviors



NIH Hypotheses for Scientific Study

More Effective

- Detect diversion **sooner** (before addiction/injury)
- Detect diversion missed by current methods (as measured by fewer false negatives)

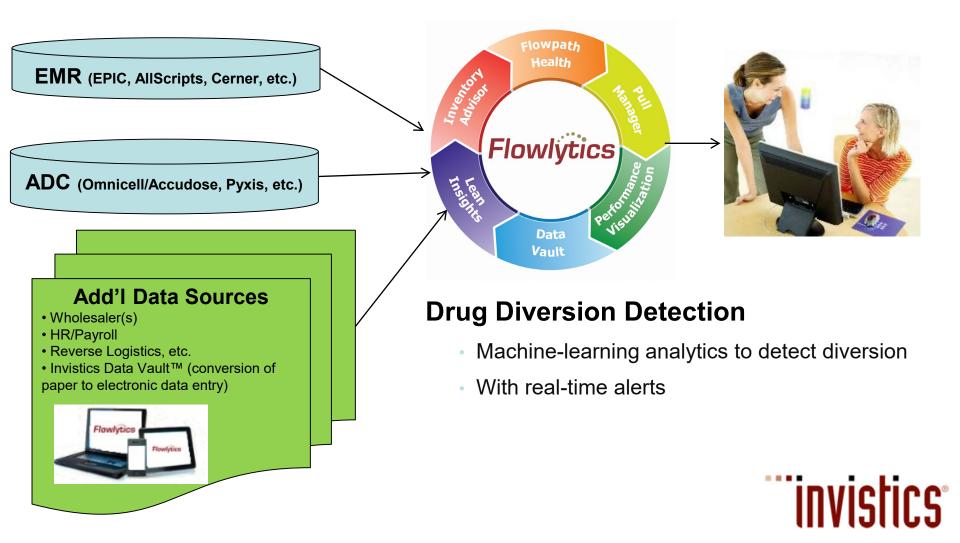
=> Lower risks to patient safety, DEA fines, etc.

More Efficient • Aut

- Automated reconciliation of all HCWs
- Manual investigations drop from hours to seconds (as measured by fewer false positives)

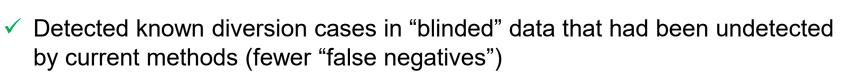
=> Lower costs to stay compliant

Data Integration: Looking Beyond the Automated Dispensing Cabinet (ADC)



Phase 1 Results & Case Study: Detected Diversion Earlier, with 100% Accuracy

- ✓ Partnered with Piedmont Health System, with:
 - mature diversion prevention (per JC)
 - numerous "known" diversion cases
- Extracted and consolidated data & case files
- Built advanced analytics & machine learning
- Detected suspicious/non-compliant behaviors



- ✓ Results:
 - 100% accuracy across 9 nursing cases
 - Every case was detected much earlier by the software
 - Notable example: diversion detected on Day #2 vs. Day #45

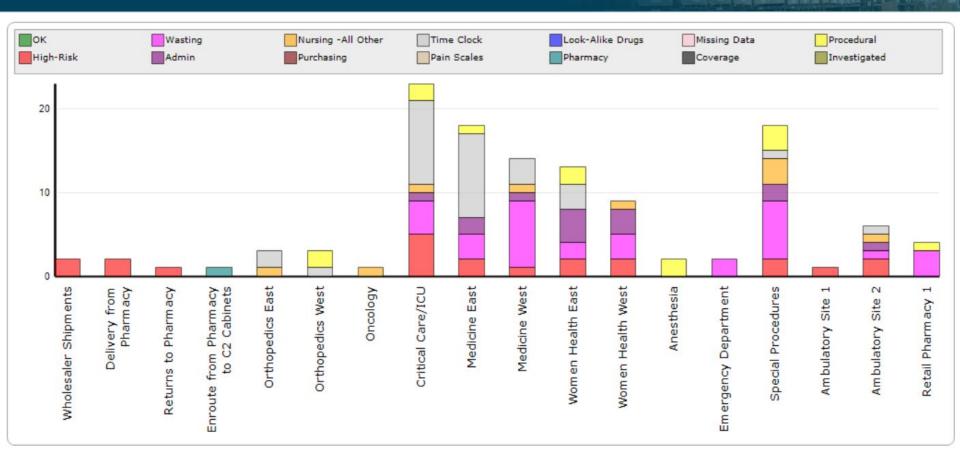




Phase 1 Example Case: Nurse 1191 detected diverting first day on job, 45 days before impaired behavior was first noticed



Diversion Detection Examples



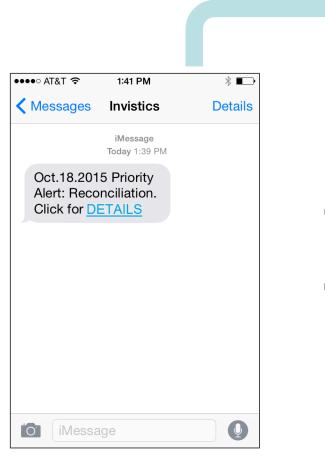


Diversion Detection Example

BATCH	BATCH DETAILS																	
		Enterprise: Acme Hospital		Controlled Substanc		nce: All	Location:		All		Ŧ							
		DEA Reg	gistration	All		-	Flow P	ath: All		~	Status:	All			Ŧ			
To Excel								To Excel	To PDF									
1	NDC	Drug	Patient PHI	Dispensed By	d Dispensed Date	Dispensed Time	Dispensed Quantity	Admin. Date	Admin. Time	Admin. Quantity		Status		Wasted Date ↓	UOM	Invest	t Location	
005	42-5	Fentanyl IV, 2 mcg/kg	LINK	Nurse Smith	h 05/26/16	5:30 AM	4	05/26/16	5:45 AM	2	CS Accountab	pility		05/26/16	cc	NO	Nursing Unit 4 Ea	ast
004	87-2	Fentanyl IV, 4 mcg/kg	LINK	Nurse Jone	s 05/26/16	4:45 AM	2	05/28/18	6:15 AM	0	Manual invent	ory override			сс	NO	Nursing Unit 4 Ea	ast
002	28-3	Fentanyl IV, 1 mcg/kg	LINK	Nurse Jone	s 05/31/16	7:00 AM	2	05/31/16	8:30 AM	1	Not Wasted wi	ithin 30 min				NO	Nursing Unit 5 Ea	ast
005	42-5	Fentanyl IV, 2 mcg/kg	LINK	Nurse Willia	05/31/16	10:00 AM	4	05/31/16	12:00 PM	2	Not Wasted wi	ithin 30 min				NO	Nursing Unit 5 Ea	ast
004	87-2	Fentanyl IV, 4 mcg/kg	LINK	Nurse Smith	h 05/31/16	9:30 AM	3	05/31/16	2:30 PM	2	Not Wasted wi	ithin 30 min				NO	Nursing Unit 5 Ea	ast
002	28-3	Fentanyl IV, 1 mcg/kg	LINK	Nurse Davis	s 05/31/16	11:00 AM	2	05/31/16	11:45 AM	1	Not Wasted wi	ithin 30 min				NO	Nursing Unit 5 Ea	ast
#43	4	Pump Key # 434	LINK	Nurse Willia	05/26/16	6:00 AM	1				Pump key not	returned withi	in 4 hrs		KEY	NO	Nursing Unit 4 Ea	ast
005	42-5	Fentanyl IV, 2 mcg/kg	LINK	Nurse Davis	s 05/26/16	7:00 AM	1	05/26/16	7:45 AM	0	Pyxis Count D	iscrep.			сс	NO	Nursing Unit 4 Ea	ast
002	28-3	Fentanyl IV, 1 mcg/kg	LINK	Nurse Smith	h 05/26/16	6:45 AM	3	05/26/16	9:45 AM	2	Waste not rep	orted in 4 hrs			cc	NO	Nursing Unit 4 Ea	ast



Real-Time Alert Example e.g., for a Nurse Manager



- Highest priority alerts send a text to Nurse Manager
- Click the message to see the alert on your cell phone



Hello xguan@invistics.com,

NEW ALERTS

The following new Flowpath Health alerts have been triggered for the Acme Health System Enterprise per your notification settings:

Initial Detection	02/01/19 11:52
Alert Rule Name	High-Risk
Alert Rule Description	Alert to Notify When User Has a High-Risk Alert Regarding a CS-II Drug
Link To Item	https://flowlytics-healthcare.invistics
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Link To Item	https://flowlytics-healthcare.invistics



Advanced Analytics & Machine Learning Example

REPORTS +NEW -

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FIELDS

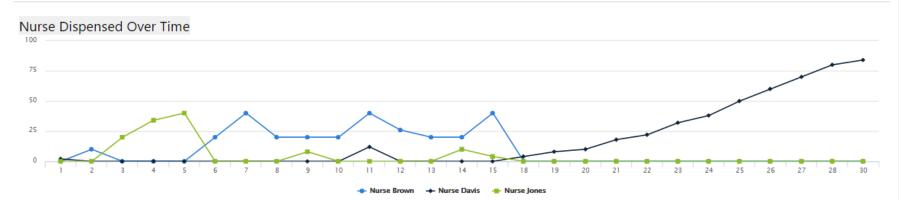
FILTERS

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Drug Reconciliation Dispensing - Hospital (Hospital Demo)

Select Date Range:	Select Location:	Select Health Care Worker:	:
1/1/2017	AHOSP		
12/31/2017		Nurse Brown	
12, 31, 201,		Nurse Davis	
		Nurse Jones	
		Nurse Moore	

❶ UPDATE RESULTS



Nurse Brown

DRUG	DISPENSED DATE	DISPENSED TIME	DISPENSED QUANTITY	ADMIN DATE	ADMIN TIME	ADMIN QUANTITY	WASTED DATE	WASTED TIME	WASTED QUANTITY	STATUS
Fentanyl IV, 1 mcg/kg	1/2/2017	11:00 AM	!	51/2/2017	11:10 AM		51/2/2017	12:00 PM	0	OK
Fentanyl IV, 1 mcg/kg	2/6/2017	10:00 AM	1	02/6/2017	10:15 AM		42/6/2017	10:45 AM	2	CS Accountability
Fentanyl IV, 1 mcg/kg	2/7/2017	10:30 AM	2	02/7/2017	2:30 PM		142/7/2017	3:00 PM	6	Late Admin
Fentanyl IV, 1 mcg/kg	2/8/2017	4:00 PM	1	02/8/2017	4:00 PM		82/8/2017	4:55 PM	2	OK
Fentanyl IV, 1 mcg/kg	2/9/2017	1:45 PM	1	02/9/2017	4:45 PM		62/9/2017	5:20 PM	4	Late Admin
Fentanyl IV, 1 mcg/kg	2/10/2017	12:00 PM	1	02/10/2017	12:00 PM		22/10/2017	12:55 PM	4	CS Accountability
Fentanyl IV, 1 mcg/kg	2/11/2017	2:40 PM	2	02/11/2017	2:40 PM		142/11/2017	3:30 PM	6	OK
Fentanyl IV, 1 mcg/kg	2/12/2017	10:15 AM	1	02/12/2017	10:15 AM		62/12/2017	11:20 AM	2	CS Accountability
Fentanyl IV, 1 mcg/kg	2/13/2017	10:00 AM	1	02/13/2017	4:45 PM		62/13/2017	5:20 PM	4	Late Admin
Fentanyl IV, 1 mcg/kg	2/14/2017	4:00 PM	1	02/14/2017	4:00 PM		62/14/2017	5:00 PM	4	OK
Fentanyl IV, 1 mcg/kg	2/15/2017	3:00 PM	2	02/15/2017	3:00 PM		182/15/2017	4:15 PM	2	OK
Fentanyl IV, 4 mcg/kg	1/12/2017	8:00 AM		31/12/2017	8:16 AM		31/12/2017	8:30 PM	0	OK

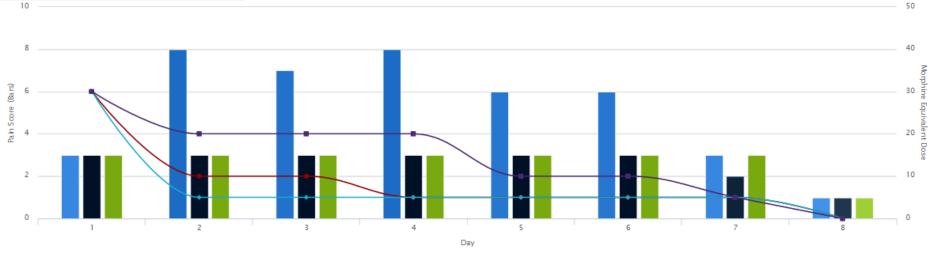
Advanced Analytics & Machine Learning Example

Hospital Pain Scores V2 (Hospital Demo)



O UPDATE RESULTS

Pain Score & Admin. Quantity by Day



🗾 Nurse Brown 🔳 Nurse Davis 📒 Nurse Jones 🔶 Nurse Jones_2 🔶 Nurse Davis_2 📲 Nurse Brown_2

HEALTH CARE WORKE	R Average Pain Score	Average Admin Quantity Per Day	Average MED
Nurse Brown	5.25	2.38	14.38
Nurse Davis	2.63	1.00	7.50
Nurse Jones	2.75	1.25	8.75

TRANS_NUMBER	HEALTH_CARE_WORKER	DIAGNOSTIC CD	DRUG	ADMIN_DATE A	ADMIN_QUANTITY	MORPHINE EQUIVALENT DOSE	PHI_EMR_#	PAIN SCORE
204-1345	Nurse Brown	K44	Morphine 15 MG Oral Dosage	1/1/2017 3:00:00 AM	2	30.00	XYZ-215	3.00
204-1346	Nurse Jones	K44	Morphine 15 MG Oral Dosage	1/1/2017 9:00:00 AM	2	30.00	XYZ-215	3.00
204-1347	Nurse Davis	K44	Morphine 15 MG Oral Dosage	1/1/2017 6:00:00 PM	2	30.00	XYZ-215	3.00
204-1348	Nurse Brown	K44	Hydrocodone 5 MG Tablet	1/2/2017 3:00:00 AM	4	20.00	XYZ-215	8.00

Phase 2 Results To Date: Detecting Diversion that was previously undetected

- Partnering with seven hospitals, with variety of:
 - workflows, e.g., pediatrics
 - IT health systems
 - diversion prevention policies
 - sizes and geographical locations
 - Automated, real-time data extracts & alerts
- Discovered novel innovations for risk scoring
- Rigorous confirmation of alerts as "true positives"
- Rapidly expanding coverage, e.g., NIH increased our grant twice
- Current Focus in 28 hospitals:
 - Effectiveness: Detect previously unknown diversion cases not detected using current methods (fewer "false negatives")
 - Efficiency: Reduce "false positives" compared to current methods
- Building nationwide database of all known drug diversion incidents in healthcare
 - Launched HealthCareDiversion.org on May 1, 2019.
 - Presenting at IHFDA Annual Conference Sept 2019 in Orlando, FL



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Are you interested in collaborating?

- on this NIH study?
- on HealthCareDiversion.org?
- Would you like to see a demo of the software?
- If so, email me at <u>tknight@invistics.com</u>
- We welcome questions, suggestions, and collaboration!

Thank you,

Tom Knight

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