

How E-connected medicine will change the value of pharmaceuticals

Overview of current initiatives on digital pill

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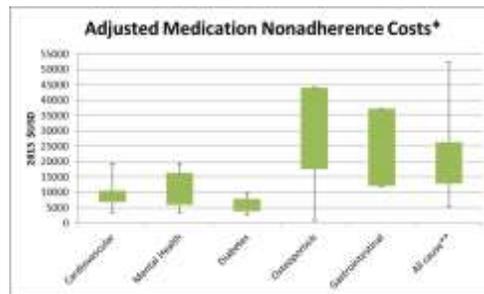
ISPOR Asia Pacific 2018

Agenda

- Burden of non compliance
- Overview of the potential advantages of current digital pills initiative from various perspectives
 - Patient
 - Caregiver
 - Doctor
 - Provider
- Effectiveness and efficiency and consideration in HTA evaluation

Burden of non compliance

- Recent study estimated that the annual adjusted disease-specific economic cost of non-adherence per person ranged from \$949 to \$44 190 (in 2015 US\$) ¹



¹Rachelle Louise Cutler et al. BMJ Open 2018;8:e016982

Simple initiative often not sufficient

- A very large randomized clinical trial (53 480 enrollees of a pharmacy benefit manager) did not show a statistically significant difference in adherence was found between those in the control group and those who received a reminder device (pill bottle strip with toggles, digital timer cap, or standard pillbox)¹

¹JChoudhry NK. Effect of Reminder Devices on Medication Adherence: The REMIND Randomized Clinical Trial. JAMA Intern Med. 2017 May 1;177(5):624-631.

Current initiatives

- Severe Mental Illness¹
 - In 2017 U.S. regulators approved the first medicine with an embedded sensor to help keep track of whether patients with mental illness are adhering to their prescriptions.
- Hepatitis C^{2,3}
 - Denver Health is conducting study using digital pill to track adherence and compliance of Hepatitis, a viral disease that impacts the liver and can be fatal but is also curable through often expensive medicines.
- Opioids³
 - Denver Health is conducting study using digital pill to track adherence and compliance

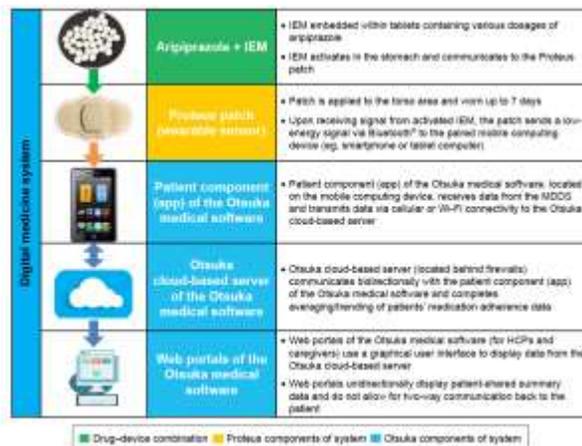
¹<https://www.otsuka-us.com/discover/articles-1075>

²<https://www.denverpost.com/2018/05/10/hepatitis-c-treatment-denver-research/>

³Chai et al. Med Internet Res. 2017 Jan 13;19(1)Digital Pills to Measure Opioid Ingestion Patterns in Emergency Department Patients With Acute Fracture Pain: A Pilot Study.

Severe Mental Illness

- Principle of Digital medicine system (DMS)¹



¹ Neuropsychiatric Disease and Treatment 2018;14 553–565

Benefits (1/2)

- The pill will allow doctors to track better than ever how well people stick to a course of medication.
 - Understand the reason for poor efficacy
- Will support the caregiver in helping patient monitoring treatment intake and decrease anxiety of caregiver on patient's compliance
 - Dialogue on adherence and reassurance
- May also discover vital new information about treating hepatitis C or SMIR and respond to the question on “how often you need to take your hepatitis C or SMI medication to be cured”¹
 - Infor; development strategy and new vision of adherence

¹<https://http://theweek.com/speedreads/793404/meet-worlds-first-digital-pill>

Benefits (2/2)

- For opioid determining adherence to a prescribed medication regimen and measuring the ways in which patients ingest as-needed medications pose methodological challenges with usual methods
 - patients determine opioid ingestion dose and frequency based on temporal perception of pain
 - thus common measures of adherence (eg, smart pill bottles, pharmacy refill histories, or patient diaries) are impractical or provide aggregate measures that cannot delineate temporal patterns of opioid ingestion¹.
- Precise measures of opioid ingestion patterns are important because they can suggest incomplete treatment of pain, the development of tolerance, or the transition into problematic use²

¹ Chai et al. Med Internet Res. 2017 Jan 13;19(1)Digital Pills to Measure Opioid Ingestion Patterns in Emergency Department Patients With Acute Fracture Pain: A Pilot Study.

² DN, Dhalla IA. Dependence and addiction during chronic opioid therapy. J Med Toxicol. 2012 Dec;8(4):393–399

Concern

- DMS can be seen as a form of surveillance and may be experienced as intrusive, coercive, or an invasion of privacy by people who experience mental illness¹
- There are legitimate reasons people may be mindfully nonadherent to prescribed medication regimens, such as psychological resistance to treatment, wishes to avoid undesirable side effects burdensome medication costs, a lack of trust in providers' advice, and treatment goals that may conflict with those of their providers— including attempts to decrease medication use.
- Behavioral psychology acceptability
- Absent strict legal orders, people have the right to manage their medications without oversight or covert pressure.

¹ Dotolo D et al. A Hard Pill to Swallow: Ethical Problems of Digital Medication. Soc Work. 2018 Aug 22.

Discussion

- Digital pill is a promising new tool that
 - Should be mandatory in clinical trials
 - could benefit patients, caregiver and doctors
 - Open a new field of the most important clinical pharmacology topic
 - Enhance value for payer and society
- Will allow researchers to understand better the use of medications in a unprecedented way that could influence the development of new drugs
- However ethical concerns must be consider so this tool does not become a coercive tool