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Panel Discussion Innovative Measures Ingestion Sensor Based Technology

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Disclosures

• No commercial disclosures

Definition of Adherence

- The extent to which a person's **BEHAVIOUR** coincides with medical or health advice -- Haynes, 1979
- Drug dosing history defined by size of doses, timeintervals between doses & duration of treatment.
- Satisfactory Medication Adherence is achieved when the gaps between a patients dosing history and the prescribed dosing regimen have little or no effect on therapeutic outcome. (John Urquhart/Terry Blaschke)

Dominant 21st Century Technology

- We are all 'wired', carrying cell phones
- 'Wired' means means real-time data transfer
- Optimal Adherence System? Accurate measurement of medication ingestion to provide dosing history, utilizing WiFi/Cellular networks to relay realtime data



Digital Health Feedback System

- DHFS incorporating edible ingestion sensor technology developed by Proteus Digital Health (PDH), Redwood City, CA.
- First technology that allows date- and time-stamping of actual ingestions of oral medications.
- Designed as a self-management tool.
- Allows remote viewing of ingestion data in near real-time

Edible Sensor

- Microchip, 1 x 1 x 0.45 mm, coated with very thin layers of commonly ingested excipients (minerals and metals)
- The active layers are thin films of magnesium and cuprous chloride with a gold under-layer that acts as current collector











Patient Set Up



Patients Change Patch and Follow Progress



Clinical Safety and Approvals

No adverse events occurred in relation to sensor from >20,000 human ingestions

Some self-limited skin rashes at patch site (<10%)

July 2015 FDA cleared for the measurement of adherence.

FDA approval for Abilify Mycite (apiprazole tablets with sensor) Oct 2017

Digitizing Medications: combination with edible sensor

- a) Edible sensor-in-Tablet Assembly 'Abilify Mycite'
- b) Edible sensor-on-Tablet Assembly
 using transparent
 excipients for
 attachment.
- a) Co-Encapsulation



Co-encapsulation

- Repackaging evaluated by randomized cross-over PK (Rifamate , Isoniazid)¹
- Dissolution and/or PK (Rifinah, Genvoya, Truvada, Descovy, Tivicay, Odefsey)²
- Dissolution (multiple)³
- No difference in coencapsulated and native drug.

1 & 3 Browne SH, Peloquin C ,Benson C, Blaschke TF et al Clin Pharmacol Ther. 2018 Mar;103 (3):502-510

2. Browne SH, Hahnan N, Schooley R, Benson C, Blashke TF et al. Under Review





Captures longitudinal drug dosing patterns



Rifamate® 150 mg / 300 mg Pattern



Can support medication adherence



TB: 'Wirelessly Observed Therapy' WOT VS DOT

- 75 Active TB patients in continuation phase
- The Positive Detection Accuracy of WOT 98.4% (CI 97.5-99%)¹
- WOT outperformed DOT in randomized study ²
- 1. Browne SH et al 48th Union Conference on Lung Health, Guadelahara Oct. 2017
- 2. Browne SH et al. CROI Boston 2018

Table 2: The percentage of confirmed /prescribed doses for DOT and WOT analyzed at the group and individual level

DOT

UIOT

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		וטע	WOT	P-value
7	Total number of confirmed	2372/3808	7326/7574	
days	doses/ prescribed doses	Mean 62.3 %	Mean 96.7%	
	Median percent (%) of	63.6 (58.3, 67.6)	97.7 (95.5, 98.3)	< 0.001
	confirmed doses for each			
	subject (95% CI) ^a			
5	Total number of confirmed	2372/2720	5263/5436	
days	doses/ prescribed doses	Mean 87.2%	Mean 96.8%	
	Median percent (%) of	89.9 (82.2, 95.2)	97.9 (95.7, 98.8)	< 0.001
	confirmed doses for each			
	subject (95% CI) ^a			

Notes: ^a Percent calculated at the subject level (total number of confirmed doses/ total number of prescribed doses for each subject) CI = confidence interval

Ongoing Studies

- TB Treatment
- HIV Treatment
- PrEP



#whenwellnessworks

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