Smart Pills for In-vitro Diagnostics

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http://www.medtronic.com/covidien/en-us/products/motility-testing/smartpill-motility-testing-system.html

Digital Health Includes Data from Intestines

The smart pills of **digital health** are separate and distinct from over-the-counter supplements or off-label use of prescription drugs advertised to ***make you smart***. Although the use of nutraceuticals and medical approaches to staving-off dementia are worthy subjects, this report focuses on the use of ingestible sensor-transmitters for diagnosis along the digestive tract.

An example of the **smart pill system** is shown in the picture above. Though not to scale, the components of the diagnostic tests are recognizable as:

1) an ingestible capsule capable of collecting data and transmitting it
2) a data collection device carried by the patient externally, (older, bulkier equipment was carried in a shoulder-bag that could be put on a bedside table at night)
3) a diagnostics program which interprets the data (pressure, pH, transit time, temperature, etc.) so the doctor(s) can provide correct diagnosis and proper treatment
4) the smart pill itself is not intended to be recovered

A smart pill system can replace **several other diagnostic procedures**. It is an ambulatory test, so patients are not required to remain in a health care facility.

The monitor may be returned to the doctor's office (as is shown in the picture above) for the data to be uploaded, or the data may be transmitted by the patient through a web portal. Diagnostic information provided includes gastric emptying time, colonic transit time, whole gut transit time and pressure patterns from the stomach (antrum) and the first portion of the small intestine (duodenum).

Labor Force Takeaway

Medical advances such as smart pill diagnostics can be expected to reduce *growth* in the number of X-ray technicians and staffing at colonoscopy centers. The number of fecal tests run through diagnostic labs may drop. Yet the number of staff coordinating data collection and analysis can be expected to grow.

TAN recommends incorporating smart pill and other advanced diagnostic techniques into training for X-ray technicians and regulatory affairs upskilling classes.

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Tracking Gastrointestinal Performance

When all is **well in the adult digestive tract**, digestion is easily ignored. When all is not well, it can become serious quickly. An explanation of how food and liquid move through the digestive system is described below:

1. Swallowing. Initially swallowing is voluntary. Once it begins, though, the process becomes involuntary and continues under the control of nerves. Muscles, triggered by the autonomic nervous system, propel food and liquid through the throat in a wave-like movement, called **peristalsis.**
2. The esophagus (aka gullet) connects the throat with the stomach. Where they join, there is a ring-like valve (sphincter) that controls passage. When food nears the closed ring, surrounding muscles relax allowing passage into the stomach, whereupon it closes again. Peristalsis moves food in the stomach.
3. In the stomach, food is stored, heated and chemically broken down by digestive juices. Muscles in the stomach mix the food-batch until it is ready to be emptied into the small intestine (bowel).
4. The small intestine continues to digest the food (now called **chyme**) with help from the **gallbladder**, **pancreas** and **liver** as it moves along a circuitous track. Nutrients are absorbed through the intestinal walls. Here the muscles propel chyme in synchronized contractions called **segmentation**.
5. Waste products, including undigested fiber, older cells that have been shed from the **mucous membranes (mucosa)** lining the intestines and an ingestible sensor if it is there, move into the large intestine, the greater part of which is called the **colon**. Waste products in the colon usually remain for a day or two as water is reabsorbed by the body and feces are expelled in a bowel movement.

With a system that complex and interdependent, there is much that can go wrong. Exactly where and how the system is compromised is essential to successful treatment.

There are two primary types of diagnostic smart pills worth highlighting. Innovation is continuing, so this list is not meant to be comprehensive.

Camera: A **pill-cam endoscopy system** allows for direct visualization of the small intestine, especially the mucosa, lesions, obscure bleeding or evidence of anemia. Traditional endoscopy of the gastrointestinal tract can go in through the nose or anus. Some cases require a small incision. In both cases sedation is required. An endoscope consists of a tube with light delivery system, optics and a camera to record transmission of optical images/video. Endoscopic biopsy or surgery can be performed with a properly fitted endoscope, but not with a pill-cam.

Pill cams do not require sedation and are ambulatory. These systems offer advanced image processing algorithms to aid in diagnostics, saving medical staff time.

Motility Testing: Motility refers to the ability to move food through its digestive tract both through peristalsis and segmentation. **Motility disorders include**: Gastroesophageal Reflux Disease (GERD), partial obstruction, bacterial overgrowth, fecal incontinence and chronic constipation. Autoimmune diseases such as Lupus and **Sjogren's syndrome** can lead to paralysis of internal organs, including gallbladder, pancreas and liver.

Traditional **comprehensive motility tests** often involve the ingestion of a radioactive material followed by X-ray imaging; these are not ambulatory. A **smart pill traveling** through a patient with autonomic nervous system problems can take a week.

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