Health Informatics from the FDA Perspective

University of Maryland Dietetic Internship Joint Class Day Workshop “Nutrition, Communication and (Nutrition) Informatics” Harbor Hospital, Baltimore, MD

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Outline

• FDA
  – Origins
  – Organization
  – What it does, and how
  – Size
• Health informatics
• FDA Office of Health Informatics
• FDA Food/Health Informatics
• Other OHI Projects
Origins of FDA- 1

1906 Federal Food and Drugs Act

Harvey Wiley
Chief Chemist, 1883-1912
Division/Bureau of Chemistry
Department of Agriculture
Origins of FDA- 2

Food Materials and Their Adulterations

By Ellen H. Richards

Instructor in Sanitary Chemistry in the Massachusetts Institute of Technology

Printed 1911

(1906, 1898, 1885 editions)
CONDITIONS have changed with marvelous rapidity in the twenty years since this little book was written, and in no quarter more than in the food problem. The original aim of the author and her collaborators was to arouse women providers for their families to the need of a study of the materials they purchased, both from a sanitary and economic point of view.

If such study was needed then, it is tenfold more important now, since, while the women have slept, the manufacturer has kept wide awake and has employed the chemist to help him impose upon the ignorant and credulous housekeeper.

With the establishment of state and city laboratories there is not today the need of the Housekeepers’ Laboratory which the authors tried to introduce. Nearly every householder can find the information that she needs by a visit to one of these laboratories if not in the printed reports.

Housekeepers no longer need their own lab.

They can get data from their state and city labs.

1906 Federal Food and Drugs Act
FDA Organization

Congress

Bills

Requests for $

Requests

Laws, $ requests for regulations

President

Requests for $, regulations

Department of Health and Human Services

Laws, $

requests for regulations

FDA

Administer laws

Bring law-breakers to court

Sue FDA

Public
How FDA Regulates

Depending on product type, combination of:

- Manufacturers and distributors tell FDA:
  - What they make and where
  - Basics about the company
- FDA or a partner inspects facilities
- FDA inspects imports at US ports
- Manufacturers apply for permission to market their product
- FDA and partners set standards for products
- FDA receives, analyzes, takes action on reports of:
  - Problems with a product
  - Harm caused by a product
- Science to support FDA duties

www.fda.gov
Size of FDA Universe

- 20% of Gross Domestic Product
- $4.4B budget in 2014, $3/person
- 15,000 employees
  - About 5,000 stationed around the US and globe
- Visit 16,000 facilities/y
Health Informatics Definition

American Medical Informatics Association (AMIA) describes Health Informatics as:

– A scientific discipline that is concerned with the cognitive, information-processing, and communication tasks of healthcare practice, education, and research, including the information science and technology to support these tasks.
Why Health Informatics?

Health data must be protected and private.

Diverse and complex volumes of health-related data will support research, decision making, and building best practices.

Technology in healthcare (portals, electronic health records (EHRs), electronic medical devices, wearable technology, etc.)

Personalized care requires:
• good standards
• understanding the data
• how to use it effectively.

Patients are more active and demand improvements to their experience.
FDA Office of Health Informatics

Targeting solutions where health, science, informatics, and technology converge...

- Solutions that are/will be useful across FDA
- Collaborate
- Represents FDA at health informatics meetings at the Department, Government-wide, and with other organizations.
Informatics Triad

Subject area  Statistics

Programming/computing
FDA Informatics

- **Data acquisition**
  - Quality of data
  - Standard data
  - Consistent method of acquisition

- **Data processing**
  - Computable format
  - Standard format

- **Data analysis**
  - Computing tools and resources
  - Statistical tools

- **Data publication**
  - Formats:
    - Manual online queries
    - Dashboard
    - Downloadable database
    - Automated programming interface (API)

- Documentation
- Subject matter expertise
FDA Food/Health Informatics - 1

- **Data acquisition**
  Clinical, product, and environment samples during outbreaks. Historic pathogen genome data.

- **Data processing**
  Lab equipment on a network

- **Data analysis**
  Genome comparisons to ID outbreak source

- **Data publication**
  Add pathogen data
Global Substance Registration System (G-SRS)/Unique Ingredient Identifier (UNII) Database

Substances in regulated drugs, biologics, tobacco, devices, foods:
  - specific foods or components of food
  - in conventional food form or a dietary supplement
  - vitamins, minerals, herbs, or other similar nutritional substances
• Based on molecular structure and/or descriptive information
• Permanent, unique, unambiguous identifiers
• Non-proprietary, free for use in health information technology systems
• Best practices for supporting health information technology
• Joint between FDA (led by OHI) and United States Pharmacopeia
• Supporters and users:
  - United States Consolidated Health Informatics initiative
  - National Cancer Institutes Enterprise Vocabulary Service
  - VA's National Drug File Reference Terminology (NDF-RT), available through NLM's Unified Medical Language System (UMLS)
  - National Committee on Vital and Health Statistics

www.fda.gov
FDA Food/Health Informatics- 3

- Food recall enforcement reports
- Food, dietary supplements, and cosmetic adverse event reports
- Automated programming interface (API) format
- Site is hosted by OHI.
Food problem risk assessments

Develop mathematical models and other tools of:

• characteristics of the microbes, chemicals, or other toxins involved
• characteristics of impacted foods
• food production and handling practices
• level of exposure to the contaminant
• the human body’s response to the contaminant

Safety assessments

FDA uses risk assessments to:

• prioritize a risk against other public health risks
• determine and implement effective risk management strategies designed to reduce the likelihood of illness or injury.
Improved methods for early detection of shellfish toxins related to blooms
Reference Standard Sequence Library (RSSL) for Seafood Identification

Uses DNA to properly identify and label seafood
Other OHI Projects- 1

Goal: Foster innovation and develop regulatory science around next generation sequencing (NGS) methods

- An online, cloud-based virtual research space.
- Scientists (>2000) from academia, industry, health care organizations and government work together
- Create tools to evaluate NGS methods
- 40TB of human DNA data
- Regular challenges and app-a-thons

www.fda.gov
Other OHI Projects- 2

Developing app focused on patient advocacy and medical devices.

Goal: to enhance public health through citizen-centric communications.
Other OHI Projects- 3

Goal: to synthesize new knowledge and make it easier for scientists to learn a new area.

• Using (and will be) open source:
  – Semantic natural language processing
  – Scientific literature
  – Databases

• Research demonstration is on interactions between oral drugs and human gut microbiome
Other OHI Projects- 4

Goal: A method to detect that the real-time patterns of patient experience are getting worse, and for which patients.

- Uses the text in electronic healthcare notes without having to know the meaning of the text.
- Using big volumes of diverse data to advantage.
https://www.fda.gov/ScienceResearch/HealthInformatics

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