

CHE 59700-H02/CHE 49700-H01
Analytical Approach to Healthcare Delivery (Fall 2021)

A. Instructor. William R. Clark, M.D.

B. Course Description. This course provides a “real world” overview of healthcare delivery in the United States (US). The major medical technology segments (pharmaceutical compounds and medical devices) are a significant focus, including their research and development processes, regulatory framework, and market approaches. Another highlight of the course is an assessment of a series of critical medical conditions having the highest impact on the US healthcare system. Clinical cases illustrating these conditions along with case studies designed to provide practical examples of healthcare developments and challenges are included. A number of emerging healthcare developments, including precision medicine, artificial intelligence, digital health, and value-based care, are addressed. In addition, the numerous ways in which the COVID-19 pandemic has affected patients and the manner in which they receive healthcare are discussed. In lieu of examinations, a team project consisting of two oral presentations and a final report is an important aspect of the course.

While the course is relevant to a broad spectrum of students, those planning a career in the healthcare industry may find it particularly useful. The course content is geared toward students interested in the pharmaceutical or medical device industry along with those pursuing post-graduate clinical training (e.g., medical school, osteopathic school).

C. Course requirements. The course is open to all undergraduate students and all students enrolled in the Graduate School. BIOL 23000 or equivalent course is recommended but not mandatory.

D. Instructor Biographical Information: Dr. Clark is a nephrologist (kidney specialist) and chemical engineer by training. He received his M.D. degree along with specialty and sub-specialty training in internal medicine and nephrology, respectively, at Indiana University School of Medicine. In addition, he received both his B.S and M.S. degrees in chemical engineering from Purdue University, at which he is now Professor of Engineering Practice in the Davidson School of Chemical Engineering. Before joining the Purdue faculty, Dr. Clark worked in the medical device (dialysis) industry for more than 20 years in a variety of positions. Dr. Clark continues to serve as a consultant in the dialysis industry.

E. Recommended (NOT REQUIRED) Texts.

- *Guyton and Hall Textbook of Medical Physiology*, Edited by John E. Hall, Elsevier, 2016, 13th ed, ISBN: 978-1-4557-7005-2
- *Crowley's An Introduction to Human Disease: Pathology and Pathophysiology Correlations*, Edited by Emily Reisner, Howard Reisner, Jones and Bartlett Learning, 2017, 10th ed, ISBN 978-1284050233
- *Jonas and Kovner's Health Care Delivery in the United States*, Edited by James R. Knickman and Brian Elbel, Springer, 2019, 12th ed, ISBN: 9780826172723

F. Course Learning Outcomes.

- Evaluate the impact of the following conditions, from both a clinical and resource utilization (cost) perspective: coronary artery disease, heart failure, diabetes, cancer, obesity, Alzheimer's disease, chronic kidney disease, stroke, arthritis, sepsis, and acute kidney injury.
- Analyze the major segments of medical products (pharmaceutical/biotechnology compounds and medical devices) along with the regulatory framework applying to each of these segments.
- For the biopharmaceutical industry, determine the major components of the drug development process and the manner in which drug pricing factors into the risk/reward equation.

- Assess US health economics by identifying the major cost drivers in the healthcare system (hospital care; physician costs; drugs and other medical products).
- Formulate a basic understanding of the sources of health insurance coverage in the US, including the differences between government-based (Medicare/Medicaid) and commercial payers.
- Explain several evolving trends which have the potential to influence healthcare substantially in the future, including precision medicine, artificial intelligence, digital health, and value-based care.
- For COVID-19, characterize the important clinical aspects and its profound impact on the US healthcare system.

G. Course Meeting Schedule.

Lectures:	Tuesday/Thursday 4:30-5:45 PM; HAMP 1266
Presentation 1:	TBD
Presentation 2:	TBD
Final Report due:	TBD

H. Instructor Contact Information.

Professor William R. Clark – Email: clarkw@purdue.edu, Telephone: (765) 496-8647 (office); (317) 691-1438 (cell)
Office: FRNY 2158
Office Hours: TBD

I. Assessment of Course Outcomes. A weighted average grade will be calculated as follows.

Homework assignments (4): 20% of total
 Presentations (2): 40% total
 Final report: 40% of total

The grading scale will be as follows.

A: 100 – 85% of the weighted points
 B: 84.9 – 75% of the weighted points
 C: 74.9 – 65% of the weighted points
 D: 64.9 – 55% of the weighted points
 F: Less than 55% of the weighted points

Note that students with grades within 3 weighted percentage points of either the upper or lower bounds of a grade range listed above will receive a “plus” or “minus” mark, respectively, after his/her score (*e.g.*, scores between 75% and 78% of the total weighted points would earn an B–). Marks of an A– will not be given.

Group projects

At the approximate mid-point of the semester, students will assemble into groups of 2-3 and choose a high-impact clinical condition to study. Each group will provide two progress updates (Presentations 1 and 2) during the course of the semester in lieu of formal examinations. A complete written summary of each group’s assessment (Final Report) will be due at semester’s end in lieu of a final examination.

Student groups may assess a high-impact clinical condition from the list of those discussed in class or another one (with instructor approval). In either case, each group should plan to meet with Professor Clark before beginning work on the project to set expectations. The assessment will include the clinical characteristics of the disorder along with its causes, demographics, and current treatment – these topics will be presented in Presentation 1. With Professor Clark or another engineering faculty member serving as a mentor, an unmet clinical need for the disorder will be identified along with an engineering-based solution for the problem – these considerations will be the focus

of Presentation 2. For a particular disorder, the engineering approach can have a direct clinical effect (e.g., improved medical device treatment) or indirect clinical effect (e.g., novel manufacturing approach for pharmaceuticals).

J. Course Schedule

- Class #1: Introduction to the US healthcare system; basic principles
- Class #2: Cardiac disease (hypertension; congestive heart failure; coronary artery disease)
- Class #3: Obesity/metabolic syndrome
- Class #4: Diabetes
- Class #5: Cancer
- Class #6: Chronic kidney disease/end-stage renal disease
- Class #7: **Clinical case #1** (including pharmacologic management)
- Class #8: Neurologic disorders (Alzheimer's disease; stroke)
- Class #9: Inflammatory/autoimmune disorders
- Class #10: Liver disease (chronic/cirrhotic liver disease; non-alcoholic steatohepatitis: NASH)
- Class #11: ICU disorders – sepsis; acute kidney injury
- Class #12: **Clinical case #2** (including pharmacologic management)
- Class #13: Overview of biopharmaceutical industry (I)
- Class #14: Overview of biopharmaceutical industry (II)
- Class #15: **Case study #1**: Drug discovery*
- Class #16: **Case study #2**: Drug manufacturing*
- Class #17: Overview of medical device industry
- Class #18: **Case study #3**: Medical device company (Cook Biotech)*
- Class #19: Health economics (spending/financing)
- Class #20: Health insurance
- Class #21: Principles of clinical/biomedical research
- Class #22: **Case study #4**: Management of clinical data/electronic medical record*
- Class #23: Emerging Trends (I): Precision medicine
- Class #24: Emerging trends (II): Artificial intelligence; digital health
- Class #25: Emerging trends (III): Value-based care; risk-sharing initiatives
- Class #26: **Case study #5**: Entrepreneurship in medicine (formation of a healthcare start-up)*
- Class #27: COVID-19: Clinical characterization and impact on healthcare system
- Class #28: **Case study #6**: COVID-19 manufacturing supply chain*

*: Guest speakers