

CONDUCTING CLINICAL RESEARCH WHILE PRACTICING MEDICINE

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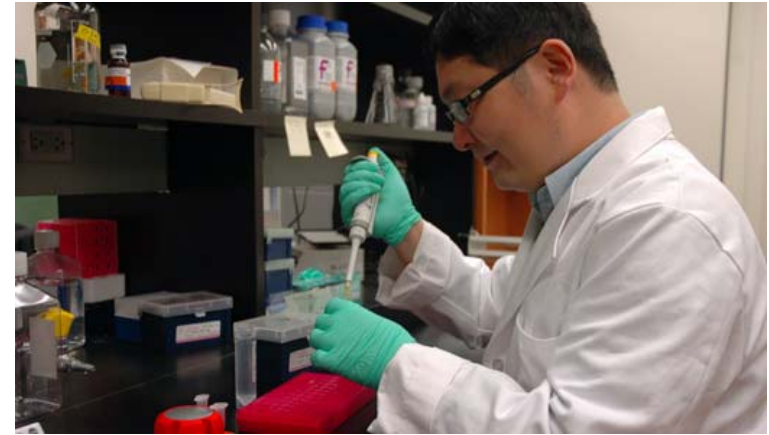
Introduction

The International Medical Editing Service believes that throughout the world insufficient attention is given to clinical research, as opposed to basic science research. Clinical research often is regarded as less important and inferior in quality.

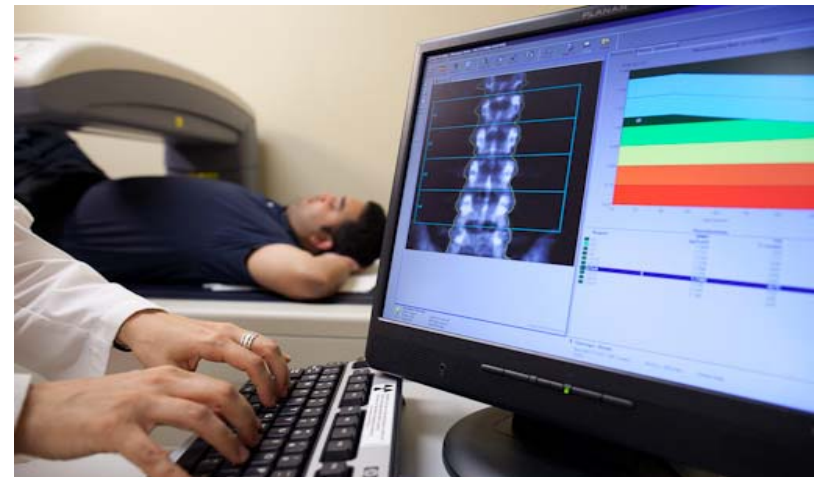
We believe that quality clinical research is essential for bringing the advances of basic research to the bedside and for achieving high-level patient care. Clinical research also has many practical advantages for the thoughtful practicing care giver who would like to advance the field of medicine.

The following short outline illustrates many of the important and attractive features of clinical research, including the opportunity to publish one's research in respected medical journals. The accompanying primer in this web site can be of great assistance for the writer of scientific research publications.

Are you familiar with these places?



Are you familiar with these people?



Clinical Research

- A branch of medical science that investigates *within medical practice*:
 - Safety
 - Risk
 - Effectiveness
 - Medications
 - Devices
 - Diagnostic tests
 - Treatment regimens

Clinical Research

- Helps physicians identify the best and current recommendations for care of patients:
 - diagnosis
 - therapy
 - cost effectiveness
 - screening
 - prevention
 - prognosis
 - risk assessment

Clinical Practice vs. Clinical Research

- Clinical practice uses:
 - established evidence-based diagnostic methods and treatment
 - individual physician experience, which may not be proven by research.
- Clinical research searches for validation of the efficacy or effectiveness of practice methods.

Examples of Clinical Research

- Comparative effectiveness (e.g., various chemotherapeutic regimens)
- Risk assessment and prediction (e.g., LDL and risk of myocardial infarction)
- Diagnostic tests (e.g., diagnostic value of AFP, CEA, gene array, oncotype)
- Randomized clinical trials

Advantages of Clinical Research

- Fewer resources needed:
 - Lab or other advanced facilities
 - Funding
 - Training
- Research can be done as part of your clinical practice, with assistance from residents and fellows (and as part of their education)
- Research results are immediately relevant and applicable to your clinical practice (no “bench-to-bedtime” delay)

What is Needed for Clinical Research?

- A curious mind and commitment to the advancement of clinical knowledge and practice
- Patients willing to participate in research
- Access to medical records--preferably electronic and available on an ongoing basis
- Dedicated, uninterrupted time--usually only a few hours per week

Clinical Research vs. Lab Research

| Basic Science Lab | Clinical “Lab” |
|--|--|
| Scientist, molecular biologist | Physician |
| Lab space | Office space |
| PCR, plate reader, centrifuge, bench, etc. | Computer, database, statistics software |
| Cells, animals, tissue specimens | Human subjects or records |
| Co-workers are physically with you and work with you | Co-workers may be distant but collaborate with you |

Clinical Research vs. Lab Research

| Basic Science Lab | Clinical “Lab” |
|---|--|
| Special lab techniques and skilled training | Basic epidemiology and statistics knowledge |
| Full-time commitment to lab | Research time part of regular clinic or practice time |
| Basic science journals (<i>Cell, Science, Nature</i>); PubMed | Clinical journals (<i>NEJM, JAMA, Lancet</i> , subspecialty journals); PubMed |
| Expensive lab facilities, equipment, technicians | Minimal cost for IT services, data assistant |
| Research grants/funding | No or minimal funding |



Professional Advantages of Clinical Research

- Academic advancement and stature
- Personal intellectual gratification
- Improvement in care and education of patients
- Satisfaction in the mentoring and development of trainees

Five Representative Clinical Research Articles (next slides)

- Relatively simple experimental designs
- Modest requirement of investigator time
- Clinically available tools (e.g., computer data bases)
- Minimal cost
- Important results with impact on clinical care
- Publication in quality peer-reviewed journals

Endoscopic papillary large-balloon dilation following limited sphincterotomy for the removal of refractory bile duct stones: Experience of 169 cases in a single Chinese center

Xiao Ming Yang, Bing Hu, Ya Min Pan, Dao Jian Gao, Tian Tian Wang, Jun Wu, Xin Ye

- An important review of experience with a complicated, demanding method, showing that it is effective and safe.
- An example of a Chinese advantage: large-population study, which would be difficult to do in most countries but can be done more easily in China.

Reference: Xiao Ming Yang, Bing Hu*, Ya Min Pan, et al. Endoscopic papillary large-balloon dilation following limited sphincterotomy for the removal of refractory bile duct stones: Experience of 169 cases in a single Chinese center. *Journal of Digestive Diseases* 2013; 14 (3) 125-131

Helicobacter pylori is a Risk Factor for Colonic Neoplasms

Amnon Sonnenberg and Robert M Genta

- Computerized database review of 156,000 subjects who had both colonoscopy and esophagogastroduodenoscopy.
- Example of a study that can be done with just computer review.

Reference: Sonnenberg A, Genta RM. Helicobacter pylori is a risk factor for colonic neoplasms. Am J Gastroenterol 2013;108:208-15

An Endoscopic Quality Improvement Program Improves Detection of Colorectal Adenomas

Susan G Coe, Julia E Crook, Nancy N Diehl and Michael B Wallace

- A clinically important assessment of colonoscopy performance.
- Simple design.
- Important results.

Reference: Coe SG, et al. An endoscopic quality improvement program improves detection of colorectal adenomas. *Am J Gastroenterol* 2013; 108: 219-226

Esophageal Stasis on a Timed Barium Esophagogram Predicts Recurrent Symptoms in Patients With Long-Standing Achalasia

W O Rohof MD, A Lei and G E Boeckxstaens MD, PhD

- Important conclusion.
- Timed barium esophagogram (relatively inexpensive and well-tolerated) rather than manometry (expensive and not easily tolerated) should be the test to decide about re-treatment of achalasia.

Reference: Rohof WO, Lei A, Boeckxstaens GE. Esophageal stasis on a timed barium esophagogram predicts recurrent symptoms in patients with longstanding achalasia. Am J Gastroenterol. 2013; 108; 49-55

Major Complications of Pneumatic Dilation and Heller Myotomy for Achalasia: Single-Center Experience and Systematic Review of the Literature

Kristle L Lynch, John E Pandolfino, Colin W Howden and Peter J Kahrilas

- Review of one institution's experience with two forms of treatment
- Pneumatic dilation has a lower incidence of complications (a very important finding).

Reference: Lynch KL, et al. Major complications of pneumatic dilation and Heller myotomy for achalasia: a single-center experience and systematic review of the literature. *Am J Gastroenterol* 2012;107:1817-25