White Paper for Patient Safety:

In search of the "BLACK BOX"
for a reliable and cost-effective quality control of the delivery of medical care.

By Gil N. Mileikowsky, M.D.

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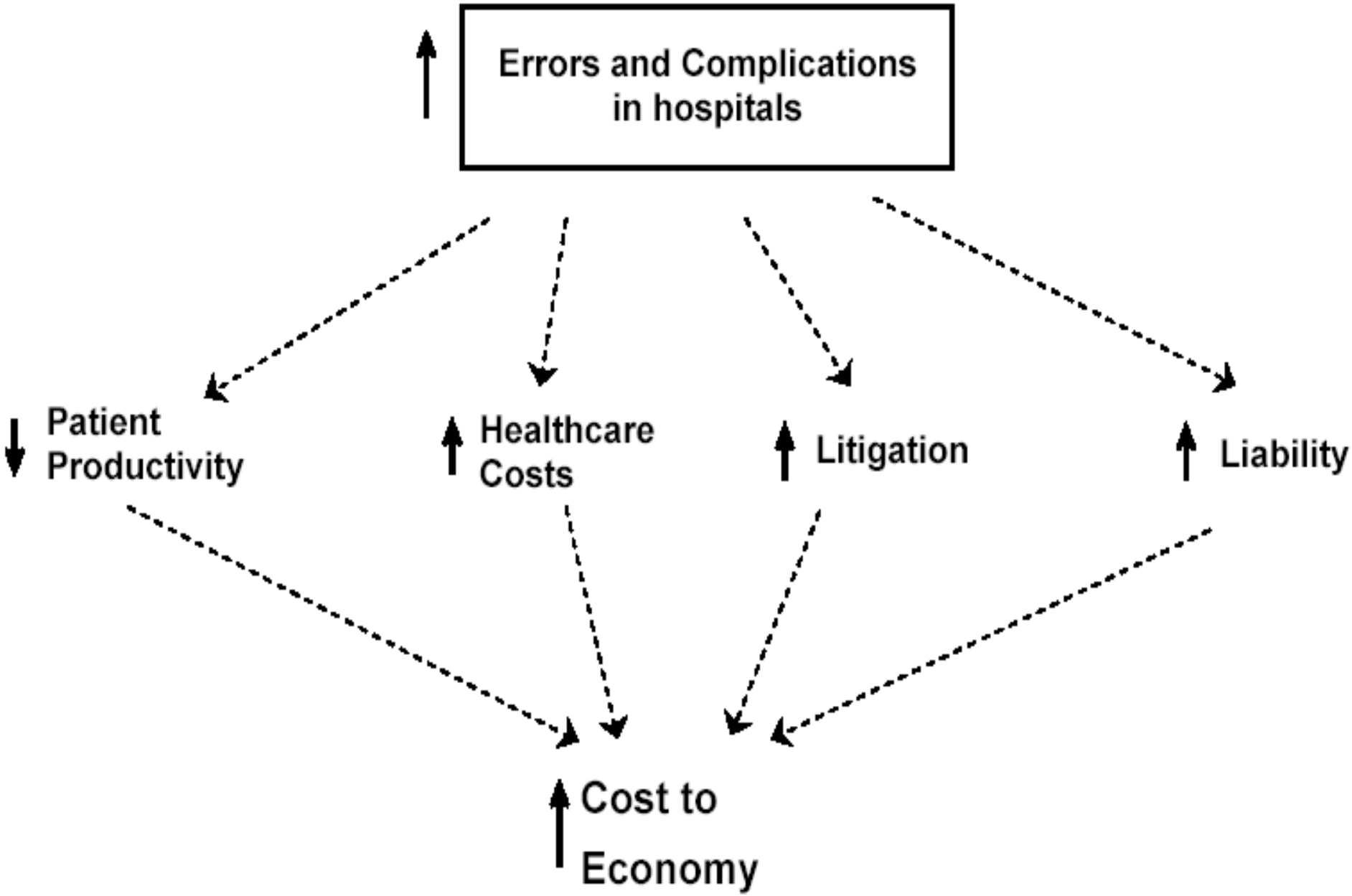
Available at:
www.aapsonline.org/mileikowsky

Lack of Patient Safety - **Economic Impact**



Organizations “supposed” to monitor hospital’s quality of delivery of care:

- **JCAHO**
- **DHHS**
- **State Medical Boards**
- **AMA**
- **CMA - IMQ**
- **HCQIA**

JCAHO

Joint Commission of Accreditation of Healthcare Organizations

" Non profit financed by hospitals."

A wholly owned subsidiary, Joint Commission Resources (JCR) is a not-for-profit organization that was established for the purpose of independently assisting health care organizations.

An additional subsidiary, JCAHO Surveyor and QHR Consultant Corporation, administers an employment program for the Joint Commission (see page 5 of JCAHO's Consolidated Financial Statements for the years ended Dec. 31 2002 and 2001).

DHHS: **Department of Health and Human Services**

There are multiple DHHS' in the country:

- Federal, State, County, City

Medical Peer Review is the responsibility of the **County's** DHHS. Unfortunately, Los Angeles County has limited resources (one physician) and a limited budget.

The office of the Inspector General (OIG) at the US DHHS has the knowledge but no jurisdiction. It acts only through the US Department of Justice to prosecute violations of the law. Hence, it cannot take action early enough to prevent errors.

State Medical Boards

Each state has its own Medical Board thus it depends on each state's budget. It is supposed to protect the consumer, yet has only jurisdiction over physicians' patient care, not over hospitals' administrators, attorneys and physicians involved in Medical Peer Review. Reports to the Medical Board are initiated by the administrators of hospitals and there is no sanction for false reporting.

AMA: **American Medical Association**

The **American Medical Association** and other medical societies have delegates to the board of **JCAHO**.

CMA: **California Medical Association**
IMQ: **Institute of Medical Quality Assurance**

IMQ is part of CMA, yet the hospitals need to ask and pay for its survey in order for the IMQ to initiate an investigation regarding Medical Peer Review and Medical Staff matters at that hospital. IMQ is part of the JCAHO survey of hospitals every three years. The IMQ staff believes that JCAHO has no jurisdiction in California regarding Medical Peer Review matters. Yet, the president of JCAHO says that it does have jurisdiction when there is no survey and competes with IMQ.

HCQIA: **Health Care Quality Improvement Act**

It is a body of laws passed by Congress, in 1986 regulating the hospitals/healthcare industry. It is also referred to as Title 42.

It provides an immunity hospitals interpret as absolute.

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"There are some who believe that this whole system has to be blown up and start over again, I happen to be one of those advocates."

Dennis O'Leary, M.D., President of JCAHO (Joint Commission on Accreditation of Healthcare Organizations) November 24, 2002,

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- Is it possible to have a “black box” in the health care industry?

- Absolutely, yes.

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- randomized “double-blind” studies
- neither the physicians nor the patients know which pill is a placebo and which pill actually contains the drug
- We can do the same when evaluating any error or complication in the health care industry.

“ Black Box ”

- Anonymous medical records, without patient’s name, hospital name, city or state.

Reviewed by:

- Anonymous licensed physicians, pharmacists, nurses, administrators, medical device manufacturers, laboratory technicians, etc. randomly selected.

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- "experts" are at times the weak link or "Achilles tendon" of the system

  - state medical boards investigations,
  - hospitals' peer review
  - medical malpractice cases
  - Medicare investigations
  - etc.

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" Two way analysis "

- Retrospective

  Following reports of errors, complications, …

- Prospective

  Preventive educational purpose and monitoring reviewers' opinions

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- Compensation for experts

1. Exorbitant fees paid by parties
2. Voluntary without any compensation

Both lead to bias

3. What is reasonable compensation ?

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a human life is valued between

4 to 9 million dollars in the US

Kip Viscusi,

economist at Harvard University

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- Human loss due to errors in hospitals in US

200,000 deaths per year

- Economic impact

800 billion dollars to 1.8 trillion dollars

HealthGrades study 2004

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US National Health Care Cost

$1.6 trillion in 2002

15% of GDP

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" We have to turn the heat up on the hospitals "

….as….

" there's no economic incentive for hospitals to reduce errors because they make more money by treating the resulting problems."

Professor Leape, MD
Harvard University-5/18/2005

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Failure of present peer review

Due to:

1. Hospital Physicians
2. Hospital Administrators/Attorneys

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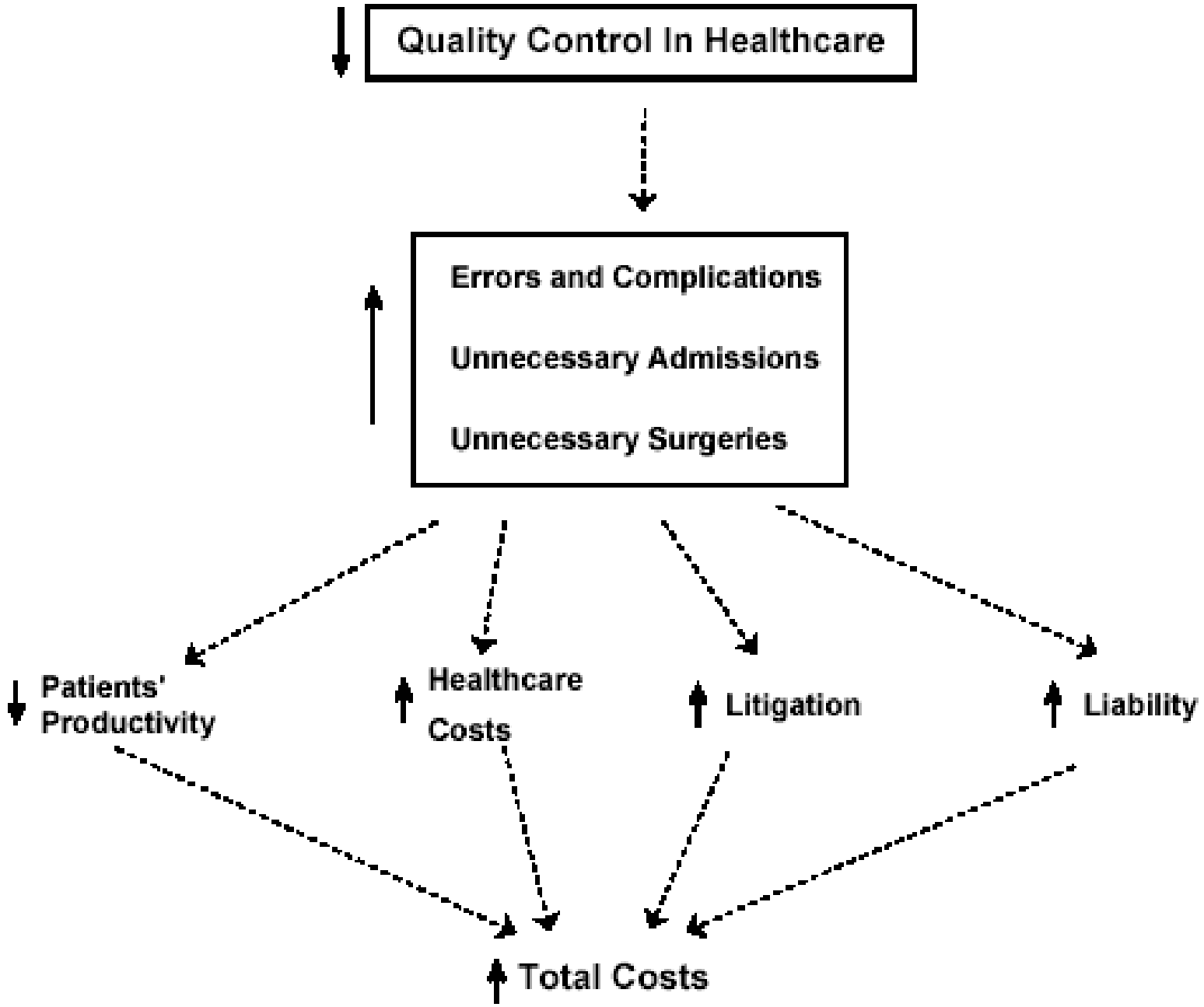
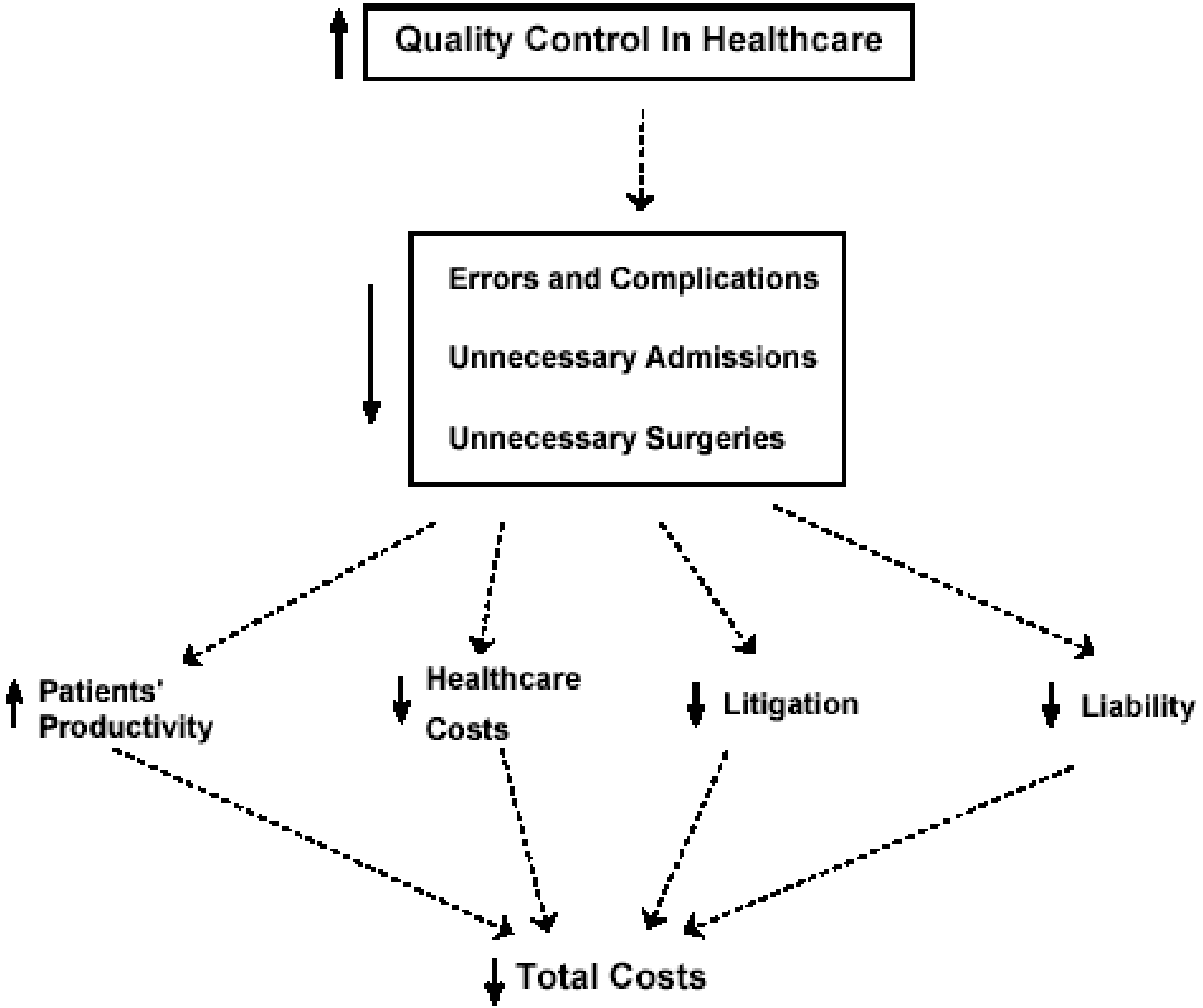
- "Errare humanum est," i.e. "To err is human"
- "Primum no nocere," i.e. "First do no harm."
- "Where there is a will, there is a way"

  Isn't that the American way ?

No Peer Review or Sham Peer Review



Legitimate Peer Review



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