

# **Dilemmas Encountered in Achieving the Optimum in Food Safety: Building the Path**

**MEFOSA WORKSHOP**

by

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**Modern technological interventions and new processes designed to:**

- 1) enhance shelf longevity, taste & quality**
- 2) meet rapidly growing demand**

**have brought the field of food science and nutrition to a new threshold of discovery.**

**But what about ethical and other dilemmas that go along with this “progress?”**

## **USE OF CHEMICALS WAS RAPIDLY INCREASING**

The Chemical Abstract Service listed slightly more than 8 million unique chemical structures in 1986, 63,000 of which are in common use and 11,500 are ingested as additives to foods or pharmaceuticals. The remaining 50,000 are potential environmental contaminants. In 2008 it listed 112,000,000 structures.

**An increase of about 12,000 structures per day**

# Era of Realization & Concern

- Thalidomide Tragedy (early 1960s)
- Adenocarcinoma of vagina and cervix in young women – link to diethylstilbestrol/ DES daughters (mid 1970s)
- Mercury poisoning in Iraq (1971-1972)
- Bread poisoning in Al-Hofuf in Saudi Arabia
- Cresyl toxicity in olive oil in Spain (1981)
- Mad Cow Disease (1996)
- Dioxin in Animal Feed in Belgium (1999)

## **USE OF CHEMICALS WAS RAPIDLY INCREASING**

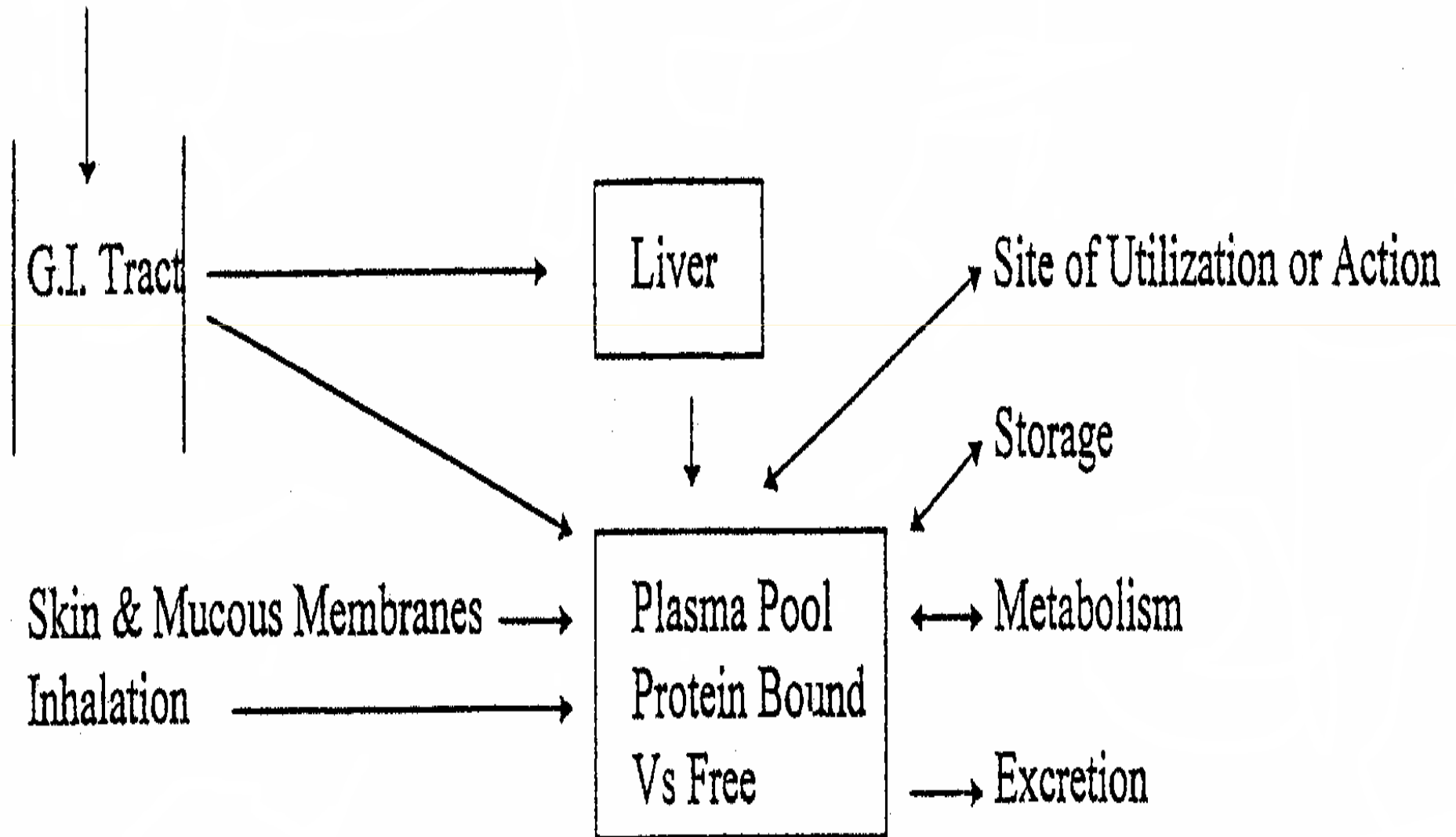
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- **Lebanon has been a victim of chemical abuse during the years of civil war. Potentially toxic waste was dumped illegally in unknown sites and pesticides abused.**
- **The subterranean water and aquifers throughout the country transport material to unsuspecting locations.**

How does the body deal with all the  
new chemicals?

## General Scheme



## **Biotransformations: Drug-Nutrient-Intoxicant Interactions**

- The human body has evolved a set of pathways for eliminating endogenous and exogenous compounds. Some of these pathways are specific while others are shared e.g Cytochrome P450.
- Steps along these pathways may become limiting and substances may interfere with each other negatively or positively at different levels in these pathways.

# Elimination = Metabolism + Excretion

- **Metabolism:**

- Biotransformation:

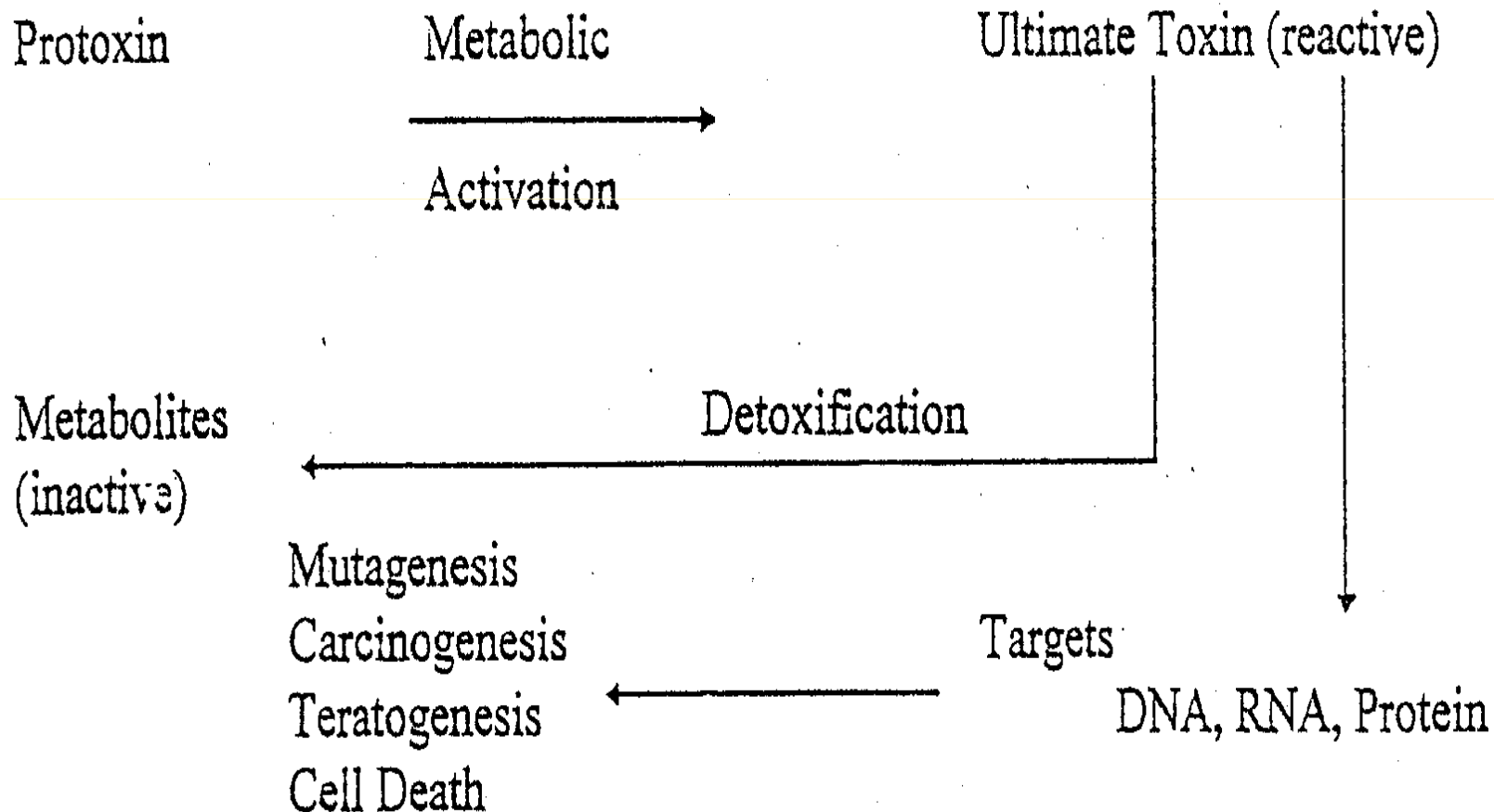
- Conversion of non-polar (fat soluble) parent drugs to polar (water soluble) metabolites resulting in either
      - Inactivation: detoxification or
      - Activation: prodrug → active drug; toxic metabolites.

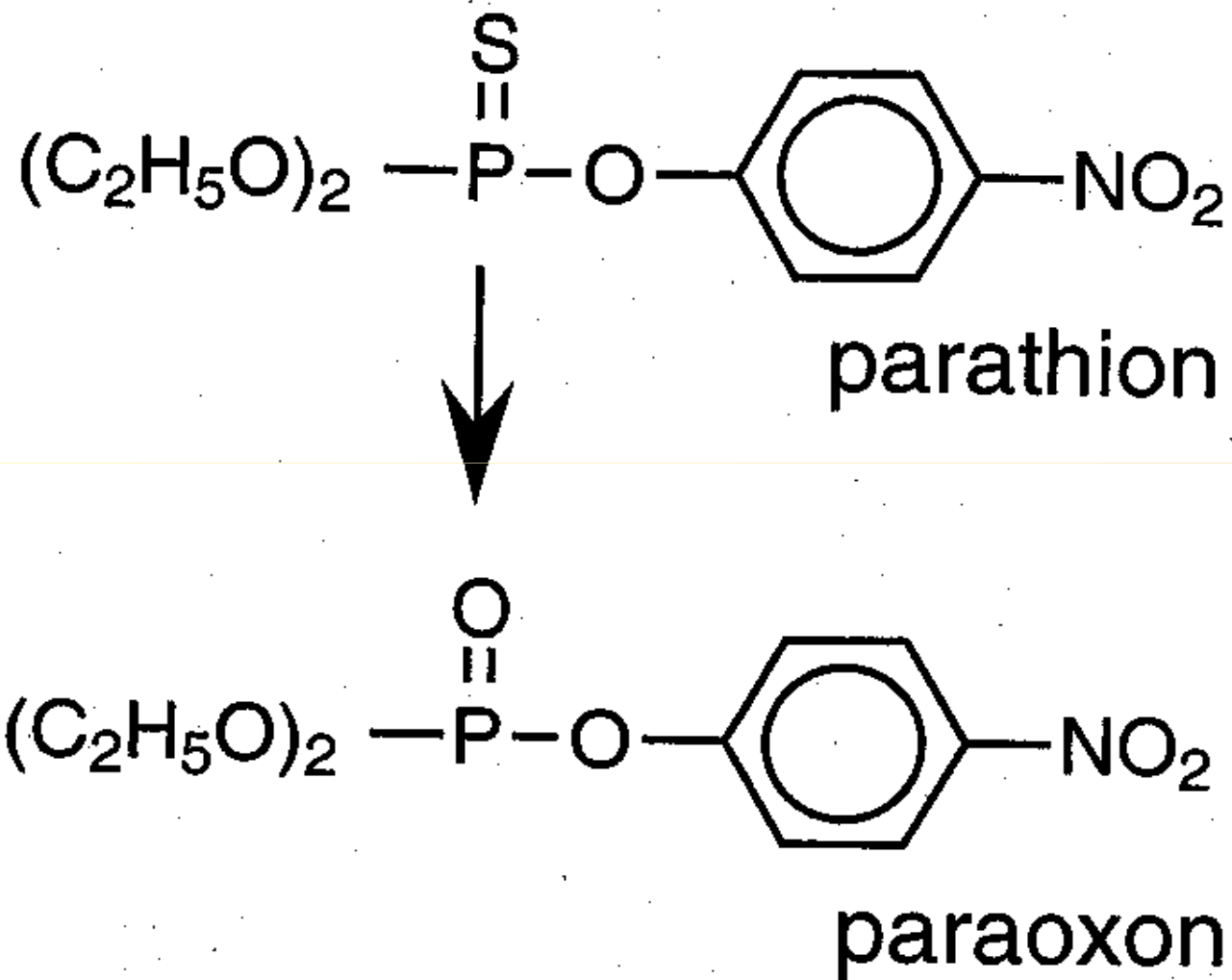
- **Excretion:**

- Loss of drug molecules (parent drug and/or metabolites) from the body.

## Role of Nutrient and Drug Metabolism in Toxicological Transformations

Biotransformation of certain substances may produce toxic metabolites that may lead to hepatitis, mutations, cancer or teratogenesis.

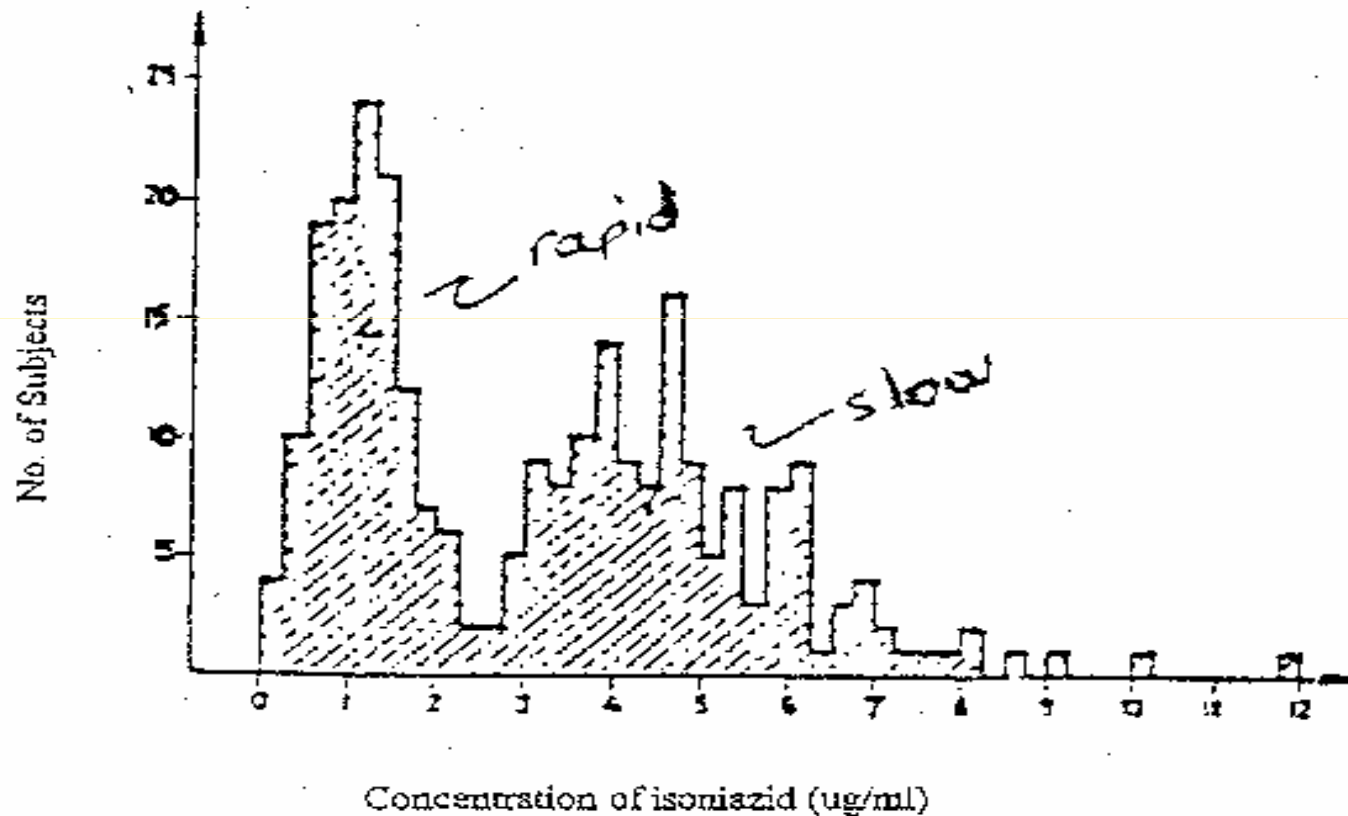




*Figure 4-2. Biotransformation of parathion.*

# Isoniazid

- polymorphism in acetylation pathway results in bimodal distribution of acetylator phenotypes



Plasma isoniazid concentrations 6 hours after drug ingestion. Results obtained in 207 members of the 35 complete family units investigated, are shown. All these subjects received approximately 9.3 mg of isoniazid per Kg of body.

## Ethnic Distribution

	<u>Percent Rapid</u>
▪ Egyptians	17
▪ W, B	45
▪ Oriental	90
▪ Eskimo	>90

-Clinical consequence – neuropathy (slow acetylators)  
but dose can be decreased to once a day.

# **RIGHT vs. RIGHT**

## **Ethical Dilemmas**

**Dilemmas for producers/handlers and consumers arise from:**

- **Conflicts between principles and interests**
  - between beneficence and economic interest
- **Conflicts due to peer and cultural pressures**
  - Use of raw eggs, supplements and organic food
- **Conflicts between protecting producers confidentiality and privacy while complying with full transparency**
  - What should the label include/how big can it be on the shelf Vs Web?
- **Ambiguous government/producer/handler and consumer relationships**
  - Issues of definitions and conflict of interest what is light/lite/diet
  - Are such terms truthful and necessary

# Types of Dilemmas

- **Genetic Manipulations**
  - Genetic alteration of plants or animals
  - Genetic testing and treatment
- **Truth telling**
- **Accidental Errors in Drug or Management**
  - Learning and drug/chemical introduction curve
  - Recording of drug/chemical use (on patient or X) charts
  - Proper labeling of drugs/chemicals
  - Automation needs to determine indices

**Establishing Proper Drug and  
Food Safety Policies and  
Procedures with Key Indicators  
require narrow  
(focused) knowledge and broad  
sociological knowledge**

# Basic principles for resolving dilemmas (Clear auditable Policies and Procedures)

- **Rule-based**: Find the one universal principle that should always apply to a situation
- **Ends-based**: Make the decision that would result in the greatest good or least risk for the majority
- **Care-Based**: Put yourself in the position of those who would be affected by the decision to decide what action you would want to be taken

**To Err is Human**

# **Statistical results of large studies on adverse events in US hospitals**

- In two studies conducted, one in Colorado & Utah combined, and the other in New York , adverse events occurred in 2.9 % and 3.7 % of hospitalizations respectively**
- 8.8% of adverse events in Colorado and Utah and 13.6% in NY hospitals led to death**

Reference Brennan et al – N Eng J Med ( 324:370-376,1991) and Med Care 2000

# **Statistical results of large studies on adverse events in US hospitals**

- In that year, there were 33.6 million admissions to US hospitals**
- It is extrapolated that of the above admissions, between 44,000 to 98,000 die each year due to medical errors**
- More people die of medical errors than from motor vehicle accidents**
- Annually 6,000 people die from workplace injury while it is estimated that about 7,000 die because of medication errors**

# Cost Resulting from Errors (USA)

- **Two out of every 100 admissions experienced preventable adverse drug event ( Bates et al (JAMA, 1997) , resulting in an average increase expenditure of \$ 1.4 million for a 350 bed teaching hospital per year.**
- **Total costs (lost income, lost household production, disability, health care costs) are estimated to be between \$37.6 billion and \$50 billion for adverse events and between \$17 billion and \$29 billion for preventable adverse events**

**Building a Safer food producing,  
handling and consuming system**

# Developing Policy for threshold improvement in Quality Food Production, handling and consumption

- Review and synthesize findings in the literature to make a list of the important Performance Improvement key indicators (e.g. in food : chemical or microbial contamination or addition). **Define the tolerable thresholds for Lebanon**
- Develop a communications strategy for raising the awareness of the general public and key stakeholders of quality of care concerns **to improve with time threshold targets and quality of care**

‘Kenneth Shine, Building a safer Health System’

- **Articulate a policy framework that will provide positive incentives to improve quality and foster accountability**
- **Encourage research that will help improve the thresholds in areas of minimal steady states**

# Examples from AUBMC

# Hospital-wide Performance Improvement Factors

**Medical Record Documentation**

**Hospital Mortality**

**Blood Usage/Blood Products**

**Medication Errors**

**Infection Control Report**

**Incidents/Accidents & Fire Risks**

**Re-admissions < 30 days**

**Re-operations < 30 days**

**Patient Family Complaints**

**Patient Care Report**

**Staff Satisfaction Surveys**

**Patient Satisfaction Surveys**

# Hospital-wide Performance Improvement Indicators and Thresholds (Dr. S. Kiblawi and the PI Committee)

Function or Process	Hospital-Wide Indicators:	Thres-hold $\Phi$	2003-2004 Yr Ave	Oct 2004	Responsibility
Medical Record Documentation	1. Cumm. Delinquent Medical Records % 2. Monthly delinquency 3. Operative Record dictation > 24 h 4. Lack of Operative record	> 49% >49 % > 5 % > 5 %	55 18 56 12	63 18 58 * 3	Ms. Leila Haider
Hospital Mortality	1. Total Number deaths per month 2. Total Number of Admissions 3. Rate: % of admitted patients 4. % of total deaths as Unexpected.	>7 %	33 1738 1.9 7.2 **	29 1618 1.8 **	Dr. Saleem Kiblawi
Blood Usage / Blood Products	1. Cross match/ transfusion ratio 2. % Audited not meeting indications 3. Informed Consent (New Policy)	> 2 > 3% > 7 %	1.5 <1	1.6 0	Dr. E. Baz
Medication Errors	1. # Medication errors (Nursing) 2. Pharmacy interventions / 100 admissions.	>50	5 5.4	2 3.9	Dr. Simaan Mrs. G Yazbeck

# Hospital-wide Performance Improvement Indicators and Thresholds - continued

Function/ Process	Indicator	Threshold	Ave	Oct	Responsibility
Infection Control (IC) Report: ***	1. Over all Nosocomial Rate	>5 %	4.7	5.1	Dr. Saleem Kiblawi
	2. Central line per 1000 line. days				
	a. ICU M/S/NS	>5.2		27	
	b. RCU	>3.4		21	
	c. CCU	>4.2		NA	
	d. PICU	>7.3		13	
	e. NICU	>7.3		15	
	3. (VAP) Ventilator associated pneumonia Per 1000 vent. days				
	a. ICU: M/S/NS	>9.4		49	
	b. RCU	>4.2		52	
	c. CCU	>4.2		NA	
	d. PICU	>2.9		10	
	e. NICU	>2.9		55	
	4. Cath. UTI/ 1000				
a. ICU: M/S/NS	>5.6		5		
b. RCU	>5.5		15		
c. CCU	>5.4		NA		
d. PICU	>4.7		NA		
e. NICU	>4.7		NA		
5. Total: SSI % of total Nosocomial	10 %		14	9	
6. Clean SSI #			5	2	
7. Needle sticks #			9	6	
			Data collection is now more consistent with and comparable to National Nosocomial Infection Surveillance System as recommended by CDC		

# Hospital-wide Performance Improvement Indicators and Thresholds - continued

Function/ Process	Indicator	Threshold	Ave	Oct	Responsibility
Occurrences Incidents/Accidents & Fire Risk	1.Number of Pat's incidents		13	6	Mr. K. Rizk. Accreditation & Risk Manager
	2.Patient falls number		1.4	3	
	3.Fire safety				
	a) Non Faculty b) Active Faculty	< 80 < 80	77 71	77 71	
Re- admitted < 30 days	1.Total # readmitted patients 2.Chemo Pat 3.IV therapy 4.Not Re-admitted 5.Not analyzed 6.Analyzed: New diagnosis Same diagnosis 7.Due to previous admission 8.Rate per 100 readmissions		286 179 11 1 3.5 99 14 81 6 2.1	Details done every 3 months 295	Dr. Saleem Kiblawi
Re-operations < 30 days	1.Total Number of Operations 2.Total Number Re-operations 3.Rate re-operations 4.Justified: # necessary non- preventable 5.Non-justified: # preventable or treatable through other means.		1169 31 2.6 29 2.3	993 16 1.6 14 2	Dr. Fayek Jamali

# Hospital-wide Performance Improvement Indicators and Thresholds - continued

Function/ Process	Indicator	Threshold	Ave	Oct	Responsibility
Patient/ Family Complaints	1.Total Number (Some combinations of categories 2 to 4)  2.Number due to system/ process  3.Number due to Medical staff  4.Number due to other staff (include Nurses)  5.Total # input in suggestion boxes. a.Compliments b.Complaints: -System/proce -Medical staff -Other staff c.Others		10  6  2.7  1.9	8+  3  3  5	Mr. John Rhoder
Patient care	1.Informed consent  2.Pain assessment (New policy)  3.Patient education (New policy)  4.Nutrition assessment done >48 hs (new policy)	Policy Modified: Approved, Forms sent for printing. Education will start when forms available for use. Compliance will be evaluated.  Nursing survey: 93 % satisfied with pain management  Nursing survey: 75 % satisfied with education; A new package of educational material is being finalized to help in education of patients: compliance with implementation will be monitored.  Screening done by Nursing, data on assessment by  dietary will be collected in 3-4 months.			Dr. Ibrahim Salti

# Hospital-wide Performance Improvement Indicators and Thresholds - continued

Function/ Process	Indicator	Threshold	Ave	Oct	Responsibility
Staff Satisfaction Surveys	1.Nursing staff 2.AUBMC staff 3.Total AUB Employees	< 90 < 90 < 90	61.84 56.63 57.67	Surveys are conducted at yearly intervals or after implementation of changes. Last survey was conducted Dec 2003 reported during April 2004	Dr.
Patients Satisfaction surveys	1.ER users  2.Hospital patients (with Nursing)  3.Clinic Patients	< 85  < 85  < 85	  93%  97 P 96 Ob	Surveys are conducted quarterly or following implementation of changes. (By Nursing Personnel)  Next planned Inpatient Survey November 2004. Next planned Private Clinic Survey in January 2005 Next Special Care survey will be for January 2005	Ms.G Mouro

\* = The JCIA and the literature do not stipulate the 24 time frame for operative report. A 48 hrs time frame may be more reasonable.

\*\*= A letter was sent to Clinical Chairpersons and Division heads requesting to report on Mortality Reviews in 2 weeks time.

\*\*\*=VAP= Ventilator Associated Pneumonia: we used only 1st episode, results not completely comparable to NNIS.

NA = Not available

Saleem Kiblawi, MD

Chairman, Performance Improvement Committee

Deputy Chief of staff/ JCIA Survey Coordinator

# Recommendations I

taken from the Institute of Medicine (USA)

- Establish protocols to enhance the knowledge base about safety- create key indicator champions
- Identify and learn from errors through mandatory reporting efforts
- Raise standards and expectations for safety improvement
- Create safety systems in health care and other relevant organizations through the implementation of safe practices at the delivery level
- Conduct with confidentiality peer reviews and shared information

# Recommendations II

## taken from the Institute of Medicine (USA)

- Create Centers for Food, Drug and Environmental Safety within governmental and NG organizations
- Develop a database through “mandatory” and “voluntary” reporting through a standardized system and perform regular analysis
- Re-license all users e.g at farm sprayers, physicians, nurses and other providers through continuing education
- Develop a curriculii on consumer/patient safety
- Enforce standards on medication/toxicant safety as is done by FDA and similar agencies

# Reccomendations III

- Establish an Authority for Food, Drug and Environmental Administration To:
  - **Develop policies and procedures for continuously improving consumer/patient/citizen safety, protection and life**
  - **Coordinate data collection and be the owner of all data and key indicators**
  - **Develop thresholds for the country and future targets**
  - **Oversee partnerships among gov. and NG stakeholders**
  - **Ensure best practices and sustainable accreditations/cert.**
  - **Take appropriate actions**