

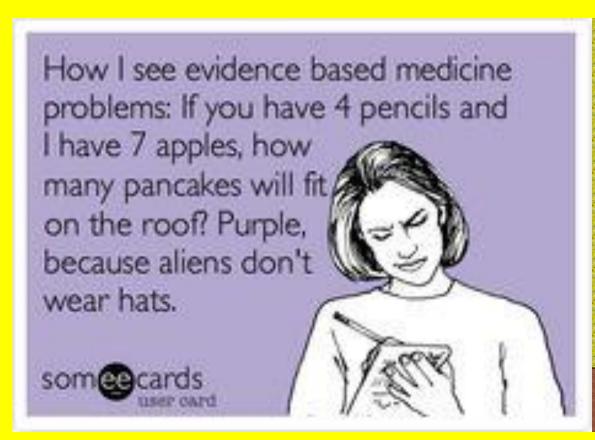


EVIDENCE BASED MEDICINE IN EMERGENCY CARE AND RESOURCE LIMITATION

FRANK PLANI

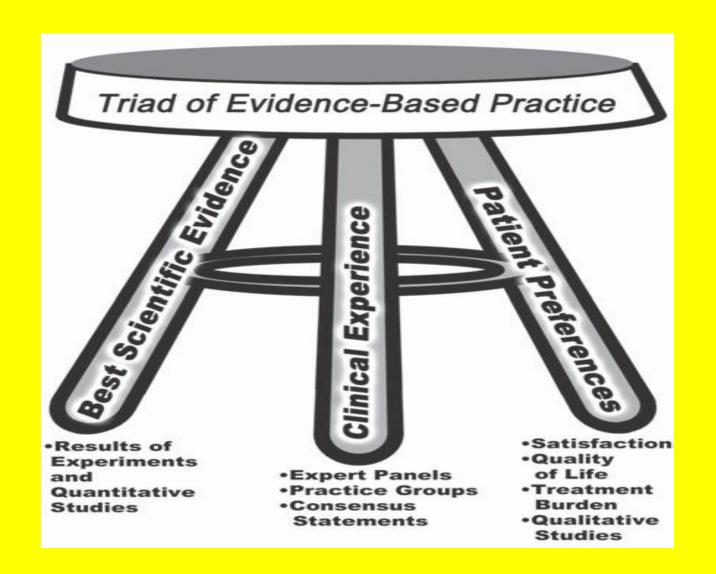
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Evidence Based Medicine does not always come natural, nor it is always the patients' first choice......





......But it is actually quite straightforward



Levels of Evidence

Randomized Controlled Trials (RCTs) "the gold standard"

Level I:

Evidence from one or more RCTs

Level II-1: Evidence from controlled trials without randomization

Level II-2: Evidence from cohort or case-control analytic studies

Level II-3: Evidence from multiple time series (observational studies)

Level III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees (ideally using formal consensus methods)

Level IV: "Evidence" based on personal anecdote ("In my experience...")

Then you decide what is best for your question

Preferred Studies to Answer Clinical Questions

Clinical Concern	Study Design of Choice		
Therapy	Randomized controlled trial (preferred); cohort, case-control, case series		
Diagnosis	Prospective, blind comparison to a reference		
Etiology or harm	Randomized controlled trial; cohort, case-control, case series		
Prognosis	Cohort, case-control, case series		
Prevention	Randomized controlled trial; cohort, case-control, case series		
Clinical examination	Prospective, blind comparison compared to the gold standard study		

The Five Easy Steps Of EBM

Step 1: Formulate your question

Define the population, the intervention, what to compare this intervention to, as well the outcome. (PICO)

Step 2: Search for the evidence

Find previous studies or research, both published and unpublished.

Step 3: Appraise the evidence

Evaluate the quality of the studies you have found. The studies of the highest quality are included in a systematic review

Step 4: Put the evidence into practice

Use the evidence to improve practice, by developing guidelines and protocols

Step 5: Monitor what has been done

Monitor what has been done, ensure that it is effective, and provide feedback

Do developing countries really need EBM?

Definitely yes, more so than in Western world

- Limited resources even more precious
- Waste even more unacceptable when needs are great and budgets small
- Often there is evidence that current practices don't work and should be abandoned
- Best evidence doesn't mean perfect evidence, rather best available; solutions need to be appropriate for setting and resources

Gap Between What We Know Is Good And What We Do

- Widespread failure to implement cost-effective health interventions
- Extra challenges in low-income countries:
 - Weak health systems, lack of professional regulation, poor access to evidence.
- Messages from systematic reviews need to be translated into guidelines
- Case studies in low-income settings show advantages of EBM practices
 - But the evidence is poor
- Promoting the uptake of evidence-based interventions should be a priority for researchers, practitioners and policy-makers.

Problems With Surgical Literature And Searches In Developing Nations

- Most common studies: Case series (44 %) and case reports (18 %)
- 43 % publications had no outcome measures
- 21 % of all publications were collaborations with developed countries

- EBM in 100 medical institutions in Europe
- Sub-Saharan Africa:3
 - 2 in South Africa and the other is their branch in Nigeria.
- SAGE/ SAMRC
- CEBHC:
 - South African Cochrane Centre
 - Effective Health Care Research Consortium
 - Faculty of Medicine and Health Sciences (FMHS), Stellenbosch University
 - Evidence Based Health in Africa

Barriers To EBM In Limited Resources

Social environment

- Media may create inappropriate demands/beliefs
- Influence of social fads and trends
- Limited patients' access to care, literacy and health behaviours

Political environment

- Ideological beliefs may be inconsistent with research evidence
- Political corruption
- Short term thinking

Practitioner

- Obsolete knowledge, attitudes
- Influence of opinion leaders may go against research evidence

Patient

- Demands for ineffective care
- Perceptions or cultural beliefs about appropriate care.

Barriers To EBM In Limited Resources

Healthcare system

- Lack of financial resources, incentives, human resources
- Lack of access to care
- Health policies that fail to promote cost-effective interventions or advocate unproven activities
- Failure to provide practitioners with access to appropriate information

Practice environment

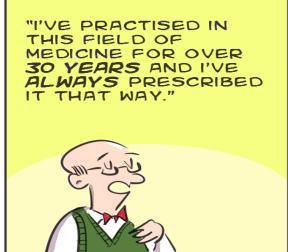
- Limitations of time
- Poor practice organization

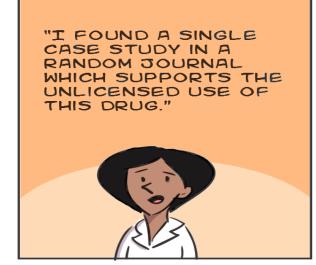
Educational environment

- Failure of curricula to reflect research evidence
- Inappropriate continuing education
- Lack of incentives to participate in education
- Influence of commercial interests (CMEs)

"EVIDENCE" BASED MEDICINE









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Reasons for the limited guidance of systematic reviews for developing countries

- 1. Lack of systematic reviews that are relevant to the health priorities of developing countries
- 2. Many interventions shown to be effective cannot be implemented in resource-poor situations
- 3. Limited amount of primary research conducted in developing countries as compared to high-income countries

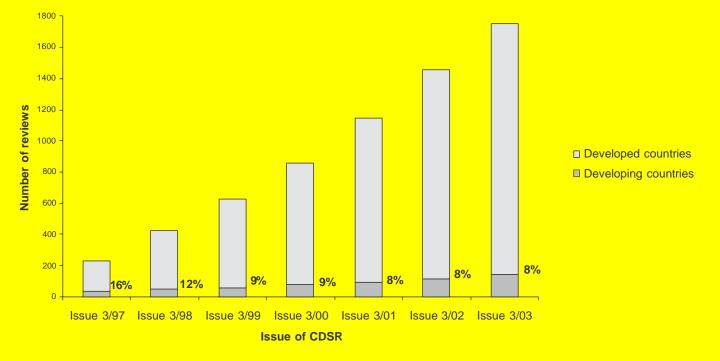
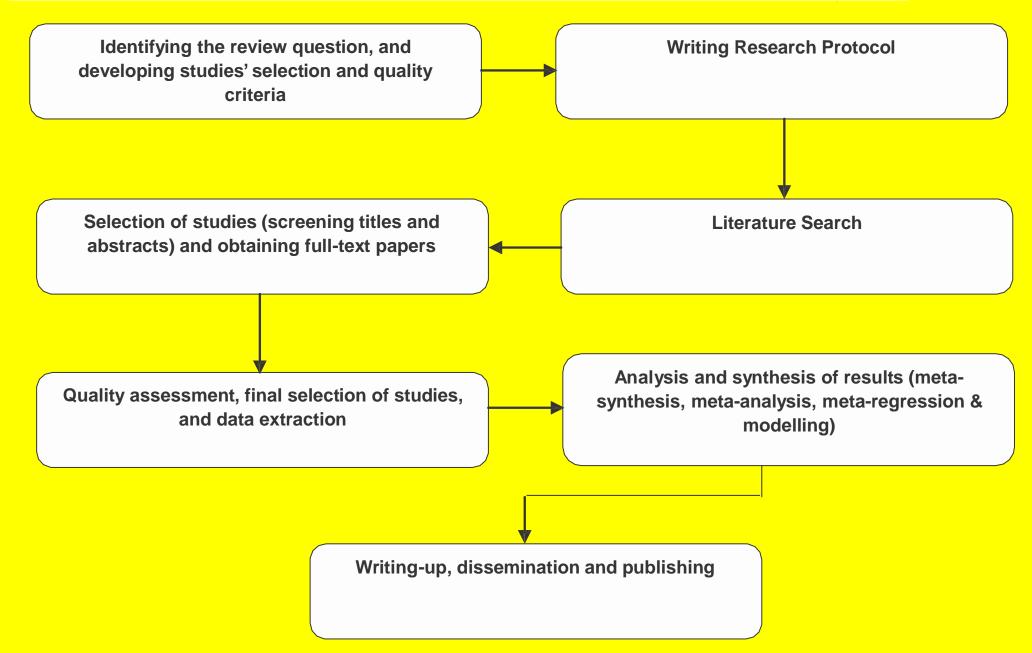


Figure 2 Number and proportions (%) of Cochrane reviews by location of contact author in developing/developed count 1997–2003.

THE 10/90 GAP: 73 billion US\$ invested annually in global health research

10% spent for the health problems of 90% of the global disease burden

Basic steps in evidence synthesis (adopted from the Cochrane Methodology)



Are My Patients Really That Different?

- 1. Are there pathophysiologic differences in the illness under study that may lead to a diminished treatment response?
- 2. Are there patient differences that may diminish the treatment response?
- 3. Are there important differences in patient compliance that may diminish the treatment response?
- 4. Are there important differences in provider compliance that may diminish the treatment response?
- 5. Do my patients have co-morbid conditions that significantly alter the potential benefits and risks of treatment?
- 6. Are there important differences in untreated patients' risk of adverse outcomes that might alter the efficiency of treatment?

Issues with populations in developing nations

- Possible patho-physiological differences in response to treatment
- Late presentations
- Self- medicating with 'prescription' drugs or traditional treatments
- Co-morbidities (i.e. malnourishment, anaemia, malaria)
- Unable or unwilling to adhere with treatment
- Cultural, behavioural and attitudinal differences
- Poor facilities and resources
- All the above would have been exclusion criteria for RCTs in developed countries

COST OF INTRODUCING EBM IN DEVELOPING NATIONS VS THE COST OF NOT INTRODUCING IT

- Challenges: Library 3 hours away, no computers, often no electricity
- BUT: Bulk of health care expenditure rests with families
- Unnecessary test done routinely:
- Resting electrocardiograms (ECG) done routinely in asymptomatic patients to screen for coronary artery disease at US \$ 5/test.
 - Enough to provide three full meals for a family of 5.
- EBM in developing countries could save millions of dollars
- Ultimate beneficiaries are the patients.
- Unregulated pharmaceutical industry: EBM provides free answers on best practice

The dangers of "Scientific Meetings"

- Heavy industry investment in "CME"s
- Nebulous distinction between drug promotion and education, and has converted society conventions into potent marketing instruments
 - Industry drivers in the Philippines: Only 17 % of hypertensive patients received beta-blockers, while 62% received calcium channel blockers!

Why EBM in developing countries is necessary and possible: No Money, Use Brain

1. Limited financial resources make provision of effective health care more vital.

Costs mainly borne out by patients

- 2. Expert opinion and personal experience are not enough Especially since doctors rely on poorly generalizable evidence.
- 3. The Cochrane Collaboration is actively encouraging participation of reviewers from poorer countries.

Cochrane Centres in Brazil, China and South Africa.

Number of systematic reviews relevant to developing countries is increasing.

WHO and World Bank are making investments in EBM

How can one do it? How to disseminate and implement EBM at your site?

- 1. Construct scenarios and pathologies common to your site along the lines of JAMA's Rational Clinical Exam: purchase a few and make copies for all clinicians
- 2. Embark on your own systematic review (usually takes 2 years or more from search to publication)
- 3. Create/formalize a series of clinical questions that will form a foundation for future research and/or Cochrane review
- 4. Focus on clinical areas that have not been previously addressed and are relevant to you

Some EBM Campaigns In Developing Nations

- Newsletters and seminars
 - Antibiotic prescriptions
- Mixed-group discussion with prescribers and patients
 - Reduce overuse of injections
- Face-to-face outreach visits
 - Improve diarrhoea treatment
- 3-month multi-media campaign to practitioners and patients
 - Early detection of colorectal cancer
- Conferences with opinion leaders
- Urinary catheter practices, infection control

Effects mostly positive but mainly non significant, and favouring more expensive projects

Obstacles and Solutions



• Experts:

- Opinionated and anecdotal
- Could they change if involved in the process?

Pharmaceutical industry:

- Enticement, CMEs, contract research
- Rewards for self regulation?

Physicians self interest:

- Fee splitting, self referrals
- Rewards for self regulation?

Dissemination and implementation of EBM in 4 Steps

Step 1: Raise Awareness about effective interventions and the potential gains

Activities

Produce and publish relevant systematic reviews

Communicate potential relevance of systematic reviews

Step 2: Target groups and individuals responsible for implementation Activities

Identify target groups, such as Health ministry policy makers, Donors, etc. Face to Face Communication and Short Summaries

Give examples of better hospital practices

Dissemination and implementation of EBM in 4 Steps

Step 3: Pilot and innovation projects of underutilized practices

Activities

Identify collaborators

Help them to stimulate and monitor change by audit, feedback and opinion leaders

Step 4: Encourage national governments, institutions, or donors to commit to evidence based approaches

Activities

Work with government and donors to establishing health technology offices Encourage national policies for evidence based guidelines and management Help institutions to train doctors, nurses, and other health staff in EBM

Example of "Introduction to EBM" Course

(Pakistan, 14 Hour Course Over 7 Weeks)

Pre-course: Berlin Questionnaire

Program, Objectives, Introduction

What Is EBM /Steps Of EBM/ Purpose Of EBM

Formulating The Question- PICO

Patient- Intervention- Comparison- Outcome

The Research Pyramid

Study Design/ Level Of Evidence/ Grades Of Recommendations

Finding The Best Evidence:

 Critical Appraisal Of The Medical Literature/ Protocols To Evaluate A Paper: Therapy/ Diagnostic Tests/ Review Articles/ Screening Tests/ Prognosis/ Causation

An Overview Of Statistics/ Glossary Of Terms

CONCLUSIONS ON ADAPTABILITY OF STUDIES

- 1. You determined that the clinical trial at hand is valid
 - 1. Therapeutic effectiveness
- 2. You demonstrated that evidence from foreign trials can be applied to the local setting without the need for repeating the RCT
 - 1. Applicability guides
- 3. You were able to determine the importance of the evidence and appreciate its application in clinical practice.
- 4. Your data can be used in giving feed-back and convincing the hospital board on the effectiveness of the treatment at hand
- 5. The EBM method also showed its value in making hospital-wide decisions.

Can You Implement EBM At Your Site?

- 1. Construct scenarios and pathologies common to your site along the lines of JAMA's Rational Clinical Exam: purchase a few and make copies for all clinicians
- 2. Embark on your own systematic review
- 3. Create/formalize a series of clinical questions that will form a foundation for future research and/or Cochrane review
- 4. Focus on clinical areas that have not been previously addressed and are relevant to you
- 5. Do not do it alone, but seek partnerships with other EBM sites

JAMA'S "Rational Clinical Examination": Lumbar Puncture

- Clinical Scenario: Previously healthy 70-year-old woman presents to ED with a 3-day history of fever, confusion, and lethargy. Uncooperative, stiff neck, GCS 13/15, CXR, urine NAD. You want to perform a lumbar puncture.
- **Context**: Diagnostic lumbar punctures (LPs) are associated with adverse events.
- Objective: Systematically review evidence about diagnostic LP techniques that may decrease the risk of adverse events and the evidence about test accuracy
- Data Sources: Cochrane Library, MEDLINE from 1966 to January 2006 and EMBASE from 1980 to January 2006 without language restrictions
- **Study Selection**: Randomized trials of patients aged 18 years or older undergoing interventions to facilitate a successful diagnostic LP or to potentially reduce adverse events and studies on accuracy

JAMA'S "Rational Clinical Examination": Lumbar Puncture

- Data Extraction: Two investigators independently appraised study quality and extracted relevant data on intervention, outcome, accuracy
- Data Synthesis: 15 randomized trials found, random-effects model was used for quantitative synthesis. Comparisons found for atraumatic needles vs. standard needles, reinsertion of the stylet, mobilization after LP, while other studies were found on accuracy
- **Conclusions**: These data suggest that small-gauge, atraumatic needles may decrease the risk of headache after diagnostic LP. Reinsertion of the stylet before needle removal should occur and patients do not require bed rest after the procedure.
 - Future research should focus on evaluating interventions to optimize the success of a diagnostic LP and to enhance training in procedural skills.

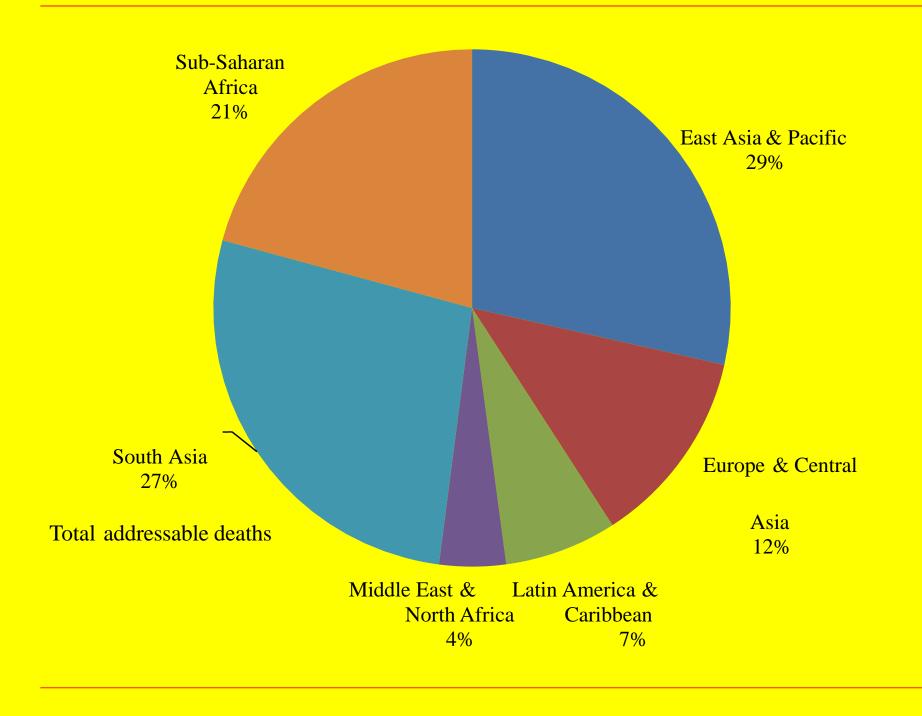
Do You Need Help? Here It Is! The 8 United Nations Millennium Development Goals

- 1. Eradicate extreme poverty and hunger
- 2. Achieve universal primary education
- 3. Promote gender equality and empower women
- 4. Reduce child mortality
- 5. Improve maternal health
- 6. Combat HIV/AIDS, malaria and other diseases
- 7. Ensure environmental sustainability
- 8. Develop a global partnership for development
 - In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries
 - In cooperation with the private sector, make available benefits of new technologies, especially information and communications
 - Globally, the proportion of the population covered by a 2G mobile-cellular network grew from 58 per cent in 2001 to 95 per cent in 2015.
 - Internet use penetration has grown from just over 6 per cent of the world's population in 2000 to 43 per cent in 2015. 3.2 billion people are linked to a global network of content and applications.

What About Emergency Care? Evidence Based Emergency Care Needed

There exists a significant burden of disease sensitive to emergency care in LMICs, but very little research on its effectiveness

- Trauma Systems have decreased mortality by 15-20% in developed nations
- 24 million deaths/year from emergency medical conditions in LMICs
 - 932 million years of life lost.



TOTAL ADDRESSABLE DEATHS: 24 MILLION

What About Surgery? Not One Of The Goals for the Millennium?

Surgical Priorities:

Malignancies

Congenital anomalies

Cataracts

Perinatal conditions

Trauma

Big Challenges:

< 50% can provide appendectomy

32% can repair congenital hernias

44% can perform caesarean sections

FACT: Minimum Rates Of Surgery 2015

- Surgical rates associated with improved health outcomes
 - Useful for benchmarking and targeted health system strengthening.
- Desirable surgical rates: 5000 operations/100 000/ year
 - Associated with a life expectancy of 74-75 years
 - Maternal mortality ratio of $\leq 100/100,000$ live births
- 13/21 World Regions, accounting for 78 % of the world's population, do not achieve this

High Income Countries (Above US \$ 12 736/P)

COUNTRY	GDP/P US\$	US\$/P HEALTH EXPENDITURE	SURGICAL OPERATIONS/ 100 000	SPECIALIST SURGEONS/ 100 000
AUSTRALIA	62 000	6 000	11 000	50
AUSTRIA	51 000	5 500	14 000	150
LUXEMBOURG	116 000	8 000	22 000	84
JAPAN	36 000	3 700	15 000	32
USA	55 000	9 400	30 000	65

Middle Income Countries

COUNTRY	GDP/P	US\$/P HEALTH	SURGICAL	SPECIALIST
	US\$	EXPENDITURE	OPERATIONS/	SURGEONS/
			100 000	100 000
ARMENIA	3 800	162	4 100	74
BOTSWANA	7 100	385	4 400	4
BRAZIL	12 000	947	6 100	32
CHINA	7 600	420	3 000	40
INDIA	1 600	75	954	7
JAMAICA	5 100	266	4 000	12
MONGOLIA	4 100	195	5 000	46
NIGERIA	3 200	118	1 600	1
SOUTH AFRICA	6 500	570	4 800	12

Low Income Countries (< US \$ 1045/P)

COUNTRY	GDP/P US\$	US\$/P HEALTH EXPENDITURE	SURGICAL OPERATIONS/ 100 000	SPECIALIST SURGEONS/ 100 000
CHAD	1 025	37	53	0
DRC	440	12	158	0
ETHIOPIA	573	27	186	1
HAITI	824	108	824	4
LESOTHO	1 034	105	2 800	1
ZIMBABWE	931	58	5 200	1

What about surgery and EBM? WHO to the Rescue!

Surgical care receives little attention and funding despite growing need

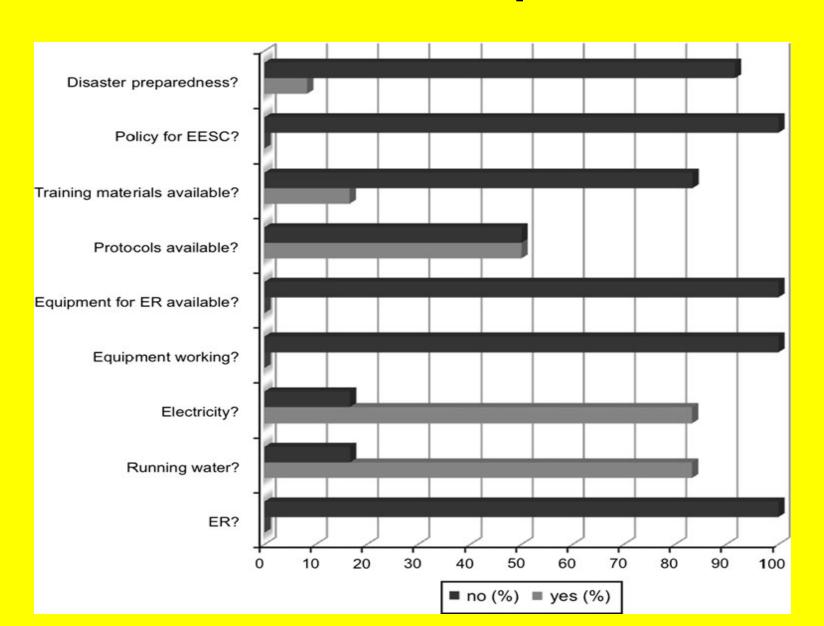
- 2004: Establishment of "Emergency and Essential Surgical Care" (EESC) to strengthen surgical services at the first-referral hospital.
- Limited data documenting the implementation and scale-up of such services

Implementation of the EESC program in Mongolia over 6 years

The perfect EBM Project:

- Phase I: Orientation, Planning, and Advocacy
- Phase II: Baseline assessment, facilitators' training, development of training materials and pilot project
- Phase III: Training of administration, project implementation, monitoring and evaluation
- Phase IV: Scale-up of services

Needs Assessment Of 12 Hospitals At The Pilot Sites



Integrated Management Of Emergency And Essential Surgical Care (IMEESC)

Teaching and reference guidelines

- Surgical care at the district hospital manual
 - Surgery, Emergency, Obstetrics, Anaesthesia, Trauma, and Orthopedics
- Evaluation of self-learning
- Training workshops
 - Trainer's guide
 - Guide to a draft agenda and program of work (model agenda)
 - Participants' evaluation
 - Sample report of training workshop

Best practice protocols

- Best practice protocols for clinical procedures safety
- Hand-washing techniques
- Waste disposal for clinical procedures
- Disaster management guidelines
- Burn management
- Postoperative care guide
- Postoperative pain management
- HIV prevention protocols

Integrated Management Of Emergency And Essential Surgical Care (IMEESC)

- Equipment lists and needs assessment
 - Essential emergency equipment generic list
 - Aesthetic infrastructure/supplies
 - Needs assessment for essential emergency room equipment
- Policy management
- Checklist of essential elements for an effective EESC service (Aide-Memoire)
- Training curriculum on emergency and essential surgical skills
- Organization and management

- Quality and safety
 - Safe surgery and safe anaesthesia protocols
 - Obstetric safety protocols
 - Monitoring and evaluation of the quality of procedures and equipment
- Research tool
- WHO situational analysis tool to assess emergency and essential surgical care

EMERGENCY AND ESSENTIAL SURGICAL CARE (EESC) LOCAL TRAINING 1

Activity/topic	Subtopics	Objectives		
Field visit		Baseline assessment of emergency care capacity, identify gaps in services and policies		
Situational analysis		Evaluation of deficiencies in health clinics		
Pre-test		Assess baseline fund of knowledge		
Pre-intervention				
surgical procedures		Baseline procedures done at site		
Organization	Triage			
Surgical safety	Correct patient, surgery, site			
	Prevention of HIV transmission			
	Disinfection and infection control			
	Waste management			
Surgical basics	Washing hands, gloving,			
	OR equipment disinfection			
	Tissue handling, suture technique, tying			
	IV access, venous cut down, injection for children			
	Methods of bleeding control			

EMERGENCY AND ESSENTIAL SURGICAL CARE (EESC) LOCAL TRAINING 2

Activity/topic Subtopics Objectives

Basic life support CPR

Airway maintenance

Shock

Critical care Care of the unconscious patient

Care of the critically injured

Trauma Principles, primary trauma care

Head, spinal, chest trauma

Paediatric trauma

Burn management

Wound care Principles

Pregnancy Labour and slow progress of labour

Pregnancy-related complications Vaginal bleeding management

Pre-eclampsia, eclampsia

EMERGENCY AND ESSENTIAL SURGICAL CARE (EESC) LOCAL TRAINING 3

Activity/topic Subtopics Objectives

Emergency surgery Intestinal obstruction,

strangulated hernia

Stomach ulcer and penetration

Abscesses, mastitis, paronychia Infections

Peritonitis, appendicitis Congenital and acquired orthopaedic cases **Orthopedics**

Anaesthesia Regional, Spinal

Drugs, toxicity

Safe use of oxygen

Ketamine use

Strengthening EESC

WHO IMEESC Tool

Post-test

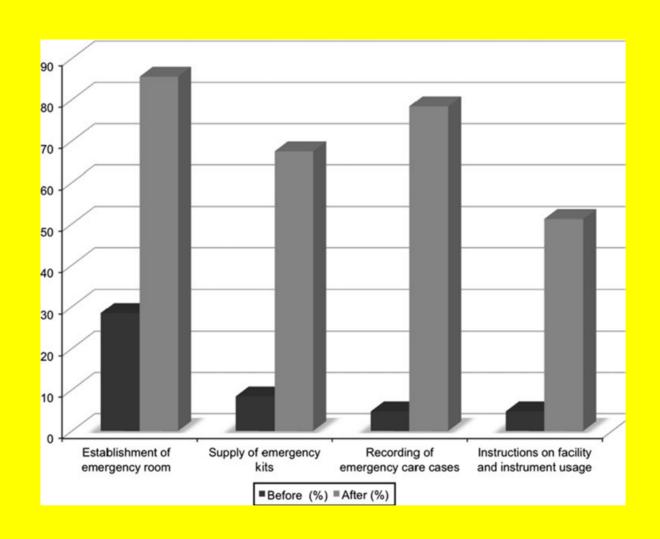
Develop a plan of action to

strengthen EESC at clinic and hospital level

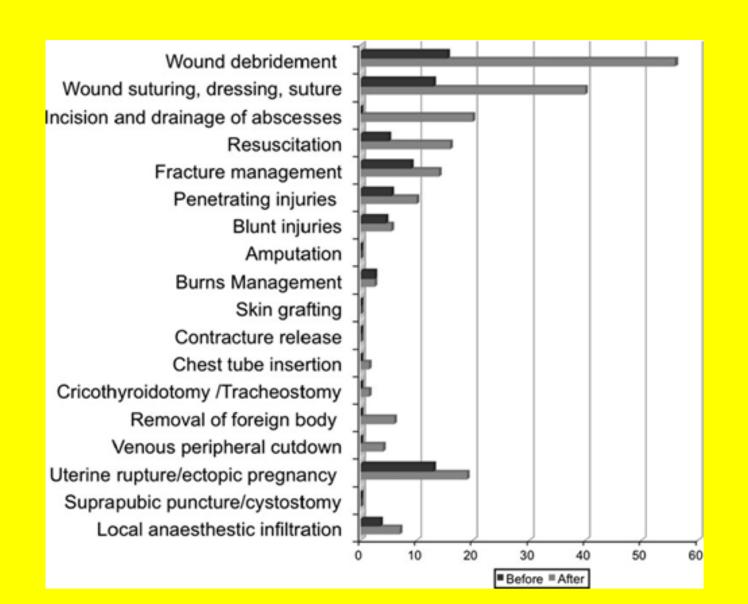
Enable trainers to use the IMEESC tool

Assess change in fund of knowledge

Results After 2 Years Of Intervention



Surgical Procedures Before And After Training



EBM Practices in Trauma and Disasters at the Trauma Units of the Wits Department of Surgery

- Evidence Based derived Guidelines are the way to practice Emergency Care
 - All International Trauma and Disaster Management Courses adhere to Best Practice principles
- Unrealistic to expect all nurses, allieds, medical students and junior doctors to attend all trauma and disaster courses
 - Free In service training provided for all medical students and junior doctors in the basics of ATLS, Hospital MIMMS and Emergotrain-equivalent
 - Free in service training for all nurses in the basics of Hospital MIMMS
- <u>Future projects</u>: Obtain favourable bank-loans for all junior doctors to attend established courses that teach EBM guidelines (ATLS, EMSB, ACLS, E-FAST), and to attend EBM courses

Conclusions

- Evidence Base is part of our daily lives
- Evidence Based Medicine is here to stay
- Resource Limitations may make it harder, but it is even more necessary
- Easier communications and international collaboration have made EBM much easier
 - Cochrane Collaboration and international organization's resources
- Human anatomy and physiology are all the same and everybody deserves the best: EBM!

