Evidence Based Medicine: How much evidence is enough?

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Objectives

Remind Participants of:

- The concepts of evidence based medicine.
- Current Basis of Health Decision Making.
- The Cochrane Collaboration and Library.
- Highlight a Review.

Background

- The science and art of medicine are dynamic and constantly changing in response to needs and trends.
- Unlimited access to medical information (consumers & providers)
- Stakeholders are demanding for quality care, best practice (patients, policymakers, HMOs etc)
- Pressure on health professionals to keep abreast is rising.
- Medical practice audits will increase.
- Litigations against malpractice are increasing.

The History

Has health decision-making always been based on best evidence?

Evolution of Health Decision-making

EBM Gordon Guyatt (1992)

Systematic Reviews lan Chalmers (1989)

RCTs Archie Cochrane (1960s)

Case reports and observational studies (1940s)

Systematic observation and critical reasoning Hippocrates

Irrational thinking and interventions (blood letting for Rx of diseases e.g. cholera)

Supernatural theory of diseases (aetiology and Rx) (pre-historic era)

The Current Basis of Decision Making Activity

- Take a moment to think back to the last time you had to make a clinical-care decision. How did you determine the best course of action?
 - Either selecting an investigation or treatment for a client?
- Please share with the group the dilemma and how you resolved it.

The Current Basis of Decision Making

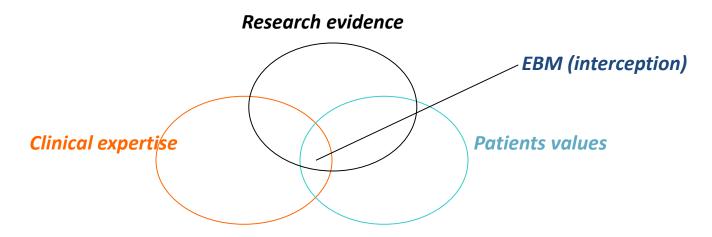
- Tradition (what we've always done).
- Anecdote (what we are told or taught) May be wrong and outdated or limited to local experience;
- Lectures and CME are frequently didactic, inadequate and their contents often outdated.
- Clinical experience & expert opinions based on individual patient encounters (?chance or wrong observations).

- Standard textbooks (often outdated by >5 years).
- Press cuttings (variable quality).
- Reasoning from patho-physiological principles (what should work) is not a guarantee as it is also evolving!
- WHO recommendations and guidelines are not always the gold standard (Expert committees and consensus opinions).

The 21st-century health care system aims at providing care that is **evidence-based**, patient-centered, systems-oriented and IT driven.

What is Evidence Based Medicine?

Evidence based medicine means basing our clinical decision making on best scientific facts (best research evidence), clinical expertise and patients preferences.



When these three elements (best research evidence, clinical expertise and patient values) are integrated, clinicians and patients form a diagnostic-therapeutic alliance which optimizes clinical outcomes and quality of life.

What is EBM not?

- Not a one-size-fits-all prescription.
- Not a replacement for experience and common sense (especially when is comes to client preference and genetic/ population differences).
- Not a big stick to wield over those who are not compliant.

Evidence-based health care

 Without current best evidence, practice will rapidly become out of date

 Need for clinical expertise to apply the evidence to individual patients

Principle of EBM

In healthcare, the overall objective is to deliver interventions that:

'do more good than harm'

Why are we still talking about EBM 23 years after it entered global medical literature and ten years after awareness started in Nigeria?

Why evidence based medicine?

- Evidence shows that research findings are translated into practice and policy slowly or not at all.
- Decisions about care interventions are still opinion-driven (medical marijuana story).
- There are still wide variation in practice without any real differences in outcomes.

- Some healthcare practices with unclear, ineffective or harmful effects are still being done.
- Still no guidelines for treating common conditions.
- There are still misconceptions about EBM among healthcare practitioners.
- There is still poor utilization of available & current research evidence in healthcare.

Evidence about some current practice

- Routine perineal shaving, enemas, routine AROM, routine episiotomy for all women; (Ineffective, potentially harmful or degrading obstetric practices)
- Megadoses of vitamin C in common cold (No proven benefit)

 Intracardiac adrenaline in cardiac arrest (Harmful)

 Short course of steroids for acute asthma & ALTB/croup (effective)

 Conservative management of anaemia (effective)

openheart

Implementation of NICE Clinical Guideline 95 for assessment of stable chest pain in a rapid access chest pain clinic reduces the mean number of investigations and cost per patient

Alvin J X Lee,^{1,2,3} Michael Michail,¹ Shumonta A Quaderi,¹ James A Richardson,¹ Suneil K Aggarwal,¹ M Elsya Speechly-Dick¹

Study showed that NICE guidelines reduced cost of investigation cost by up to 10% and the number of tests per patient.

<u>Lee AJ</u>, <u>Michail M</u>, <u>Quaderi SA</u>, <u>Richardson JA</u>, <u>Aggarwal SK</u>, <u>Speechly-Dick ME</u>. Implementation of NICE Clinical Guideline 95 for assessment of stable chest pain in a rapid access chest pain clinic reduces the mean number of investigations and cost per patient. Open Heart. 2015 Feb 19;2(1):e000151.

Evidence based approach is applicable to all aspects of Health Decision Making:

- Diagnosis/Screening
- Causation/aetiology
- Therapy
- Prognosis
- Prevention /control
- Rehabilitation (social, psychological, economic)
- Follow-up

Appropriateness of Research Design

Clinical question	Study design
Diagnosis	Cross-sectional
Screening	Cross-sectional
Aetiology/causation	Cohort or Case-Control
Therapy	Randomized controlled study (RCT)
Prevention	Randomized controlled study (RCT)
Rehabilitation	Randomized controlled study (RCT)
Prognosis	Longitudinal cohort study

The most reliable method of evaluating effectiveness is the:

RANDOMISED CONTROLLED TRIAL

RCT the 'gold standard'

- Random allocation reduces selection bias
- Allocation concealment protects the sequence of randomisation before and until interventions are given
- Blinding protects randomisation after interventions are given to participants



The biomedical literature is vast:

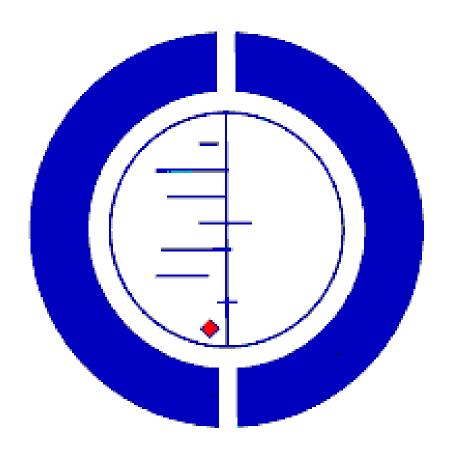
- Over 2 million articles are published annually in over 20,000 journals
- Nearly 3/4 of a million trial results (published and unpublished) exist across all areas of health care

Hierarchy of Evidence

1	Systematic Reviews of RCTs
2	RCT
3	Quasi-experimental studies (experimental study without adequate randomization)
4	Controlled observational studies (a) Cohort studies (b) Case control studies
5	Observational studies without control groups.
6	Expert opinion etc

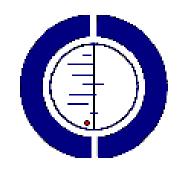
Why we need systematic reviews

- Many RCT's have already been done.
- Unwise to make decisions based on a single trial.
- Clinicians, managers, researchers and users depend on summaries of research.
- These are usually published in journals and textbooks.



THE COCHRANE COLLABORATION

Cochrane logo



- Systematic review in 1989, of steroids given to women in preterm labour
- Pooled results showed the intervention reduced the risk (by 30% - 50%) of babies dying from complications of immaturity
- Thousands of deaths could have been prevented, had the review been conducted earlier in 1972 when 1st trial was done.

The Cochrane Collaboration

 An international network of individuals and institutions committed to preparing, maintaining and disseminating systematic reviews of the effects of healthcare interventions

Founded in Oxford, UK, in 1993

The Cochrane Library

- A database of systematic reviews, abstracts, register of controlled trials, methodology reviews etc.
- Used to be published quarterly now online.
- Last count had 8841 reviews and protocols.
- Reviews are updated regularly and outdated reviews are deleted.
- Impact Factor: 5.939



Trusted evidence.
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Better health.

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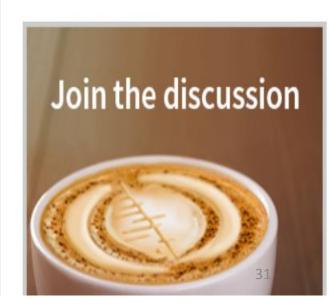
Special Collections



Farewell and thanks to Dave Sackett, Cochrane's first pilot Iain Chalmers, Andrew D Oxman 29 May 2015



Regulatory agencies hold the key to improving Cochrane Reviews of



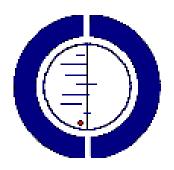
53 Review Groups

- Acute Respiratory Infections
- Breast Cancer
- Cystic Fibrosis and Genetic Disorders
- Diabetes
- Epilepsy
- HIV infection and AIDS

- Infectious Diseases
- Multiple Sclerosis
- Neonatal
- Oral Health
- Pregnancy and Childbirth
- Sexually Transmitted Diseases
- Skin

Regional versus general anaesthesia for caesarean section (Review)

Afolabi BB, Lesi AFE, Merah NA



Objective: To compare the effects of regional anaesthesia with those of general anaesthesia on the outcomes of caesarean section.

Background

Both General and Regional Anaesthesia are commonly used for CS. It is important to document which is more efficacious.

Search Strategy

Cochrane Pregnancy and Childbirth Trials Register (30 December 2005) CCRT (200%), MEDLINE (1966 – 2005) and EMBASE (1980 – 2005)

Selection Criteria

RCTs evaluating the use of RA and GA in women who had CS for any reason.

Results: Apgar Score 1 and 5 minutes

Analysis I.7. Comparison I Epidural versus general anaesthesia, Outcome 7 Mean Apgar score at I minute.

Review: Regional versus general anaesthesia for caesarean section

Comparison: I Epidural versus general anaesthesia Outcome: 7 Mean Apgar score at I minute

Study or subgroup	Epidural anaesthesia N	Mean(SD)	General anaesthesia N	Mean(SD)		ean Differe	nce Weight	Std. Mean Difference IV,Fixed,95% CI
Hodgkinson 1980) 10	6.8 (2.9)	10	5.7 (2.31)	-	-	6.7 %	0.40 [-0.49, 1.29]
Kolatat 1999	120	8.3 (1.9)	103	6.7 (2.8)		+	72.2 %	0.68 [0.41, 0.95]
Yegin 2003	31	7.38 (0.55)	31	7.19 (0.7)			21.1 %	0.30 [-0.20, 0.80]
,	161 = 1.86, df = 2 (P = 0.4 t: Z = 4.92 (P < 0.0000	,	144			•	100.0 %	0.58 [0.35, 0.81]
				-10 Favo	-5 urs general	0 5	10 enidural	

Analysis I.8. Comparison I Epidural versus general anaesthesia, Outcome 8 Mean Apgar score at 5 minutes.

Review: Regional versus general anaesthesia for caesarean section

Comparison: I Epidural versus general anaesthesia

Outcome: 8 Mean Apgar score at 5 minutes

Study or subgroup	Epidural anaesthesia		General anaesthesia	Mean Difference	Weight	Mean Difference	
	Ν	Mean(SD)	Ν	Mean(SD)	IV,Fixed,95% CI		IV,Fixed,95% CI
Hodgkinson 1980	10	7.9 (2.51)	10	8.4 (1.07)	-	1.6 %	-0.50 [-2.19, 1.19]
Kolatat 1999	120	9.7 (0.9)	103	9.2 (1.6)	-	38.3 %	0.50 [0.15, 0.85]
Yegin 2003	31	9.87 (0.42)	31	9.54 (0.67)	•	60.0 %	0.33 [0.05, 0.61]
Total (95% CI)	161		144		•	100.0 %	0.38 [0.17, 0.60]
Heterogeneity: Chi ²	= 1.62, df $= 2$ (P $= 0.44$	4); I ² =0.0%					
Test for overall effect	z = 3.47 (P = 0.0005)	2)					
						ı	

Results: Maternal Blood Loss

Analysis 1.12. Comparison I Epidural versus general anaesthesia, Outcome 12 Maternal estimated blood loss in ml.

Review: Regional versus general anaesthesia for caesarean section

Comparison: I Epidural versus general anaesthesia

Outcome: 12 Maternal estimated blood loss in ml

Study or subgroup	Epidural anaesthesia		General anaesthesia		Mear	Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	IV,Fixed	1,95% CI		IV,Fixed,95% CI
Hong 2002	13	1418 (996)	12	1623 (775)			2.0 %	-205.00 [-901.71, 491.71]
Lertakyamanee 1999	117	748.2 (363.5)	114	873.6 (403.1)	-		98.0 %	-125.40 [-224.46, -26.34]
Total (95% CI) Heterogeneity: Chi ² = 0	130 0.05, df = 1 (P = 0.82);	I ² =0.0%	126		•		100.0 %	-126.98 [-225.06, -28.90]
Test for overall effect: Z	= 2.54 (P = 0.011)							
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Main results

The data show that there is no evidence of a difference in mortality and most outcomes between GA and RA groups. However, women who had RA have significantly less blood loss and their babies and statistically better Apgar scores and 1 and 5 minutes.

Authors' conclusions

One method is not superior over the other and it is really a matter of mother's preference, available facilities and training of the surgeon.

Any Questions?



Conclusion

- Evidence Based Medicine has become the standard of quality healthcare decision making worldwide including Nigeria.
- Its is a concept that integrates expertise, research evidence and patients values and preferences.
- Evidence has to be appraised and graded and decisions should be based on the best available evidence preferably from systematic reviews of randomised controlled trials.
- EBM is dynamic and continues for as long as we remain in clinical practice.
- In answer to the question we started with how much evidence is enough? The answer: NOT ENOUGH

THANK YOU FOR YOUR ATTENTION

Useful Sources

- Effective Healthcare Research Consortium
 - www.evidence4health.org
- Cochrane Library
 - www.cochrane.org
- National Guidelines Clearing House
 - www.guideline.gov
- National Institute for Health and Care Excellence (NICE)
 - www.nice.org.uk