
EVIDENCE BASED TRANSFUSION MEDICINE

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What I want to talk about

- Defining EBM, approach in EBM, practicing EBM
- EBM and policy making
- Hierarchy of evidence (as it evolved over time) and its importance
- Application of EBM to transfusion medicine
- Landmark studies that have changed the practice of transfusion medicine
- Differences in applicability of principles of EBM to transfusion science and related policies as compared to other fields
- Where do we stand?
- Why EB approach is urgently needed in this country?

EVIDENCE-BASED MEDICINE

- Early 1990s
- clinical epidemiologist (Dr. David Sackett)
- McMaster University in Hamilton, Ontario, Canada.
- Integration of the **best research evidence** with the **best clinical expertise** and **patient values** to attain **good clinical decision making**
- A concept:
 - physicians were “**aware** of the evidence on which one’s practice is based
 - the **soundness** of the evidence
 - the **strength of the inference** the evidence permits.”

What is the approach in EBM

- It **deemphasizes** intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making
- Requires the **application of formal rules of evidence** in the **evaluation of the clinical literature**

How to practice EBM

- **Systematically finding** the best of the relevant studies
- make independent assessments (**critical appraisal**) of that evidence rather than rely on opinions offered by experts
- determine the **relevance of published findings** to the clinical problem and setting of their own patient
- critically appraise reports of **cost-effectiveness** analyses as well
- Extract **clinical message**
- **Integrate** with clinical expertise and patients values
- Solve specific patient problems (make **informed medical decision**)

EBM and Policy making

- Wider inputs:
 - roles that society and health care organizations play in providing, and in limiting, resources for health care.
 - Issues of cost-effectiveness and local resources
 - EBM dictates that, much like clinical decisions, policy decisions should also be made on the best available research evidence

Policy without evidence – malaria screening in blood banks in Pakistan (as directed by national guidelines NIH)

- **Should we screen for malaria? And how?**
 - What is the burden of transfusion transmitted malaria i.e. how big and serious is the problem?
- **Which strategy is suitable for country that is holoendemic for malaria and donors are not voluntary**
 - **Donor deferral** strategy as is being done in UK and USA, based on origin and travel history?
 - **Screening by antibody based test**, for population where majority have been exposed to malaria? How many donors will become unfit?
 - Which **antigen based test** that is sensitive enough to detect very low parasitaemia of donors?
 - ICT have sensitivity equal to microscopy but cost is many times more and those public blood banks who have procured these have wasted public money and will give false sense of security
 - **PCR** is most sensitive test (with all the other issues notwithstanding). Can any blood bank in Pakistan do it?
 - May be only option is to **treat all recipients of blood with antimalarials** (provided burden of TTM is significant)
 - efficacy and safety is proven in clinical trials

Pitfalls of not having local evidence and making guidelines from evidence not relevant to our situation

- Promoting unscientific practices
- Blocking the way for much needed indigenous research
- Wasting resources
- Not benefiting patients
- Opening doors for corruption

BEST RESEARCH EVIDENCE

- Several rankings of the strength of evidence generated by different types of **clinical research designs**
- Many types of clinical reports have been published and can be used for clinical and policy decision making process
- An assessment of the strengths and weaknesses of each study is needed

What is the common denominator for assigning strength to evidence

- Experimental vs observational studies
- Key difference:
 - Assignment of “exposure” (Intervention in context of clinical trials)
- **Exposure**: Potentially beneficial or harmful substance, clinical characteristic, or study factor that occurs prior to the outcome of interest
- **Experimental studies**: Exposure is assigned to study subject by the investigator.e.g. clinical trials
- **Observational study**: The exposure not under the control of the investigator. e.g. epidemiologic studies

Strengths of experimental designs (or the clinical trials)

- Take care of all possible factors (*in advance*) that can spoil their results so that their research will be relevant, applicable and respected
- Results and inferences can harm patients if result are taken on face value (*without critically judging*) and applied by others to their subjects
- Doctors practicing EBM know this and choose to either apply or not to apply the interventions to their patients (*make informed decisions*)

Factors affecting RCTs (experimental studies)

- **Confounding**: Situation in which an unrecognized variable (factor) is associated with both the outcome of interest and its probable cause, producing false association (concealing the truth)
- **Taking care of confounders**: Random allocation of exposure (intervention or treatment) so that play of chance should distribute confounders equally b/w groups
- **Bias**: Systematic error in the design of study (or execution) that results in a systematic deviation from truth when data are analyzed and reported.
 - **Selection bias**: removed by randomization
 - **Observation bias**: removed by blinding
- Randomized double blind studies takes care of confounders and biases and yield strongest evidence

Structured and systematic integration of information from different studies on a problem

■ Meta-analysis or statistical overview

- The disciplined synthesis of previous research findings in which the results of multiple reports on the efficacy of an intervention are compared, contrasted, and reanalyzed
 - **When the results are discrepant:** overview investigates reasons for disagreements among studies
 - **When the results are concordant:** meta-analysis, through the application of a number of quantitative techniques, measures the effect of the intervention across the combined investigations.
 - This measure is referred to as the “average” or “summary” effect of the treatment under study

Meta-analyses

- **Meta-analysis of the literature (MAL)** integrates the processed findings of previously published RCTs
- **Meta analysis of individual patient data (IPD)**
Conclusion of MAL may differ from IPD

Systematic reviews

- Systematic reviews is a form of secondary research that often include results of meta-analyses.
- A systematic review presents:
 - The characteristics of the studies
 - Information relevant to an assessment of the methodologic quality of each study
 - A tabulation of the results of the studies
 - Findings of meta-analyses only if statistical integration is both possible and appropriate

Searching tools for evidence, systematic reviews and meta analysis and RCTs

■ OVIDs

■ Cochrane Collection

- Systematic Reviews; Database of Reviews of Systematic Reviews; Cochrane Controlled Trials Register

■ Evidence Base Reviews

- **DARE**: The Database of Abstracts of Reviews of Effectiveness includes the Cochrane Database of Systematic Reviews and ACP Journal Club

- **NICE**: National institute for clinical excellence

- **The ACP Journal Club Collection**: includes **ACP Journal Club**, a publication of the American College of Physicians, and **Evidence-Based Medicine**, a joint publication with the British Medical Journal Group

■ Best Evidence

- Electronic version of ACP Journal Club
- Most information contained in commentary

- **CCTR** is a bibliographic database of definitive controlled trials

- **STARD initiative**: Towards complete and accurate reporting of studies of diagnostic accuracy

- **SRI**: Systematic review initiative in transfusion medicine

Consensus conferences

- If systematic reviews of RCTs are not available
 - fall back on “weaker” evidence
 - base one’s conclusions on observational studies or even uncontrolled clinical observations.
- EBM requires that all available evidence be considered in a disciplined and hierarchical manner
 - An assessment of all the available evidence by means of consensus conferences that compile and evaluate all available literature
 - This is opposed to canvassing “expert opinion”

Hierarchy of strength of evidence concerning efficacy of therapeutic intervention

1. Anecdotal case reports
2. Case series without controls
3. Series with literature controls
4. Analyses using computer databases
5. Case-control observational studies
6. Series with historic controls
7. Single randomized controlled trial
8. Confirmed randomized controlled trial

Green and Byar. Using observational data from registries to compare treatments: The fallacy of omnimetrics. *Stat Med* 1984; 3:361-370.

Levels of Scientific Evidence about efficacy of therapeutic intervention (Sackett DL, 1989)

Level 1: 1a) RCTs that are sufficiently large to be either:

- Positive with a small risk of being falsely positive or
- Negative, with a small risk of being falsely negative or

1b) Meta analyses of individual patient data from previously conducted RCTs

Level 2: 2a) RCTs that are not sufficiently large to confidently detect (or rule out) a treatment effect or

2b) Meta-analyses of the literature (ie. Systematic reviews integrating the processed findings of previously published RCTs

Level 3: Cohort observational studies comparing treated patients with concurrent, nonrandomized controls

Level 4: Cohort observational studies comparing treated patients with historical controls

Level 5: 5a) Case-series describing the experience of treated patients and using no controls or

5b) Expert opinion

Levels of Scientific Evidence about efficacy of therapeutic intervention

- Level 1: RCTs or meta-analyses of RCTs where the lower 95% CL of the treatment effect exceeds the minimal clinically important benefit
- Level 2: RCTs or meta-analyses of RCTs where the lower 95% CI for the treatment effect overlaps the minimal clinically important benefit
- Level 3: Observational studies with concurrent controls
- Level 4: Observational studies with historical controls
- Level 5: Case-series without controls

Cook DJ, Guyatt GH, Laupacis A, et al: Clinical recommendations using levels of evidence for antithrombotic agents. *Chest* 1995;108; 227-230

Hierarchy of strength of evidence concerning efficacy of therapeutic intervention

1. “N of 1” randomized controlled trial*
2. Systematic reviews of randomized controlled trials*
3. Single randomized controlled trial*
4. Systematic reviews of observational studies*
5. Single observational study*
6. Physiological studies’
7. Unsystematic clinical observations

*Measuring a “patient important” clinical outcomes (mortality, recovery, cancer recurrence, postoperative infection etc)

‘ Measuring a physiological endpoint (eg. Blood pressure, cardiac output, exercise capacity, bone density etc)

Guyatt G. Guides to Medical Literature. A manual for Evidence-Based Clinical Practice. [2002](#)

Grades of Recommendation in guidelines and consensus meetings

- A:** consistent level 1 studies
- B:** consistent level 2 or 3 studies **or** extrapolations from level 1 studies
- C:** level 4 studies **or** extrapolations from level 2 or 3 studies
- D:** level 5 evidence **or** troublingly inconsistent or inconclusive studies of any level

"Extrapolations" are where data is used in a situation which has potentially clinically important differences than the original study situation

Issues in blood banking and transfusion medicine needing application of EBM

- Evaluating a new therapy or medical procedure
- Evaluating a diagnostic or screening test
- Monitoring disease or disease markers

Evaluating a new therapy or medical procedure

- Begins with preclinical research including **animal testing**
- Phase I, II, III and IV studies in human subjects
- Phase III studies are pivotal **clinical trials**
- Phase IV studies are **post marketing studies**

- **Examples:**
 - Comparison of different types of platelet transfusions on subsequent formation of antiplatelet antibodies and refractoriness to platelet transfusions
 - Comparing different methods for reducing the risk of transfusion associated CMV
 - Type of transfused product was assigned by the investigator

Epidemiologic Studies (observational)

■ Why these are needed:

- Rare adverse events (frequency 1 in 1000 or 1 and 10,000) . Maybe unacceptable if severe.
- Assessment of long term use of therapy
- Eligibility in trials is restrictive
- True effectiveness of therapy in real world (post marketing surveillance or pharmacoepidemiology)

■ Examples in transfusion med:

■ **Prospective epidemiologic studies**

- Transfusion transmitted viruses study: difference of hepatitis in patients who received Tx vs those who did not
- Post operative mortality in transfused subjects vs those who were not

■ **Retrospective epidemiologic studies**

- Potential risk factors for HCV or HBsAg in blood donors

■ **Cross-sectional epidemiologic studies:**

- Telephonic survey of blood donor attitudes

Evaluation a diagnostic screening test

- Correctly classify people as:
 - Those with health related outcome or condition of interest (disease)
 - Those without disease
- Quantification of the validity of diagnostic test:
 - Sensitivity and specificity
 - Analytical sensitivity
 - Window period narrowing
 - Interference with tests
 - Positive and negative predictive value of test
- Purpose of the test:
 - to “screen out” infectious blood
 - “Screen in” asymptomatic patients
 - Consequences of false positive and false negative test may be different

Monitoring disease (surveillance)

- means for generating an initial signal that a potential problem may exist
 - Active reporting system
 - Passive, volunteer reporting system
 - Adverse event reporting system (AERS)
 - SHOTS UK Blood transfusion services
- Help to direct resources to appropriate area (both in terms of geography and subject matter)

Number 1: The TRICC trial

Hébert PC, Wells G, Blajchman MA, et al. A multicenter randomized controlled trial of transfusion requirements in critical care. N Engl J Med 1999;340:409-17.

TABLE 8. Outcomes of a multicenter RCT evaluating allogeneic RBC transfusion requirements in critical care patients (modified from Hébert¹²)

Outcomes	Liberal cohort	Restrictive cohort	P value
Number of patients	420	418	
30-day mortality (%)	23.3	18.7	0.11
MODS*	11.8 ± 7.7	10.7 ± 7.5	0.05
Length of stay			
ICU (days)	11.5 ± 11.3	11.0 ± 10.7	0.53
Hospital (days)	35.5 ± 19.4	34.8 ± 19.5	0.58
RBCs (number of units transfused)	5.2 ± 4.9	2.5 ± 3.8	<0.01
Transfusion avoidance (%)	0	33	<0.01

* MODS = multiple organ dysfunction score.

Number 1: The TRICC trial

- An allogeneic RBC transfusion threshold as low as 7.0 g per dl was at least as safe and possibly superior in terms of short-term survival, to a transfusion trigger of 10.0 g per dl.
- The restrictive transfusion strategy resulted in a 54 percent decrease in allogeneic RBC units transfused.
- 33 percent of patients in the restrictive strategy cohort avoided allogeneic RBC transfusions altogether
- All the patients in the liberal transfusion strategy cohort required allogeneic RBC transfusions.

Number 2: Prophylactic PLT transfusion threshold

Rebulla P, Finazzi G, Marangoni F, et al. The threshold for prophylactic platelet transfusions in adults with acute myeloid leukemia. *N Engl J Med* 1997;337:1870-5

- Patients transfused at a PLT transfusion trigger of 10×10^9 per L had no more bleeding episodes than those that were transfused at a higher transfusion trigger ($20 \times 10^9/L$).
- **First RCT showing the safety of decreasing the prophylactic allogeneic PLT transfusion trigger to 10×10^9 per L.**
- Seven subsequent studies, four RCTs and three observational studies, have since been published that support the conclusion obtained from this RCT.

	Trigger ($\times 10^9/L$)		P value
	10	20	
Number of patients	135	120	
Patients with major bleeding episodes (%)	21.5	20.0	0.41
PLT transfusions (mean number of units)	7.05	8.97	0.001
RBC transfusions (mean number of units)	9.57	9.07	NS*
Mortality (%)	13.3†	7.5	>0.01

* NS = not significant.
† Two-thirds of the deaths were due to infections, but there was only one hemorrhagic death.

Number 3: Plasma exchange versus plasma infusion in the treatment of thrombotic thrombocytopenic purpura

Rock GA, Shumak KH, Buskard NA, et al. Comparison of plasma exchange with plasma infusion in the treatment of thrombotic thrombocytopenic purpura. N Engl J Med 1991;325:393-7.

- Each patient was to have a minimum of seven intervention procedures done over the first 9 days, which included either plasma infusion with fresh-frozen plasma (FFP) or plasma exchange with FFP.
- Outcome data at 6 months
- **Established that plasma exchange as an effective treatment in TTP**
- Study established that plasma exchange was superior to plasma infusion alone

Variable	Plasma infusion*	Plasma Exchange*	P value
Number of patients	51	51	
Successful response	25 (49)	40 (78)	0.002
Survival	32 (63)	40 (78)	0.036

* Data are reported as number (%).

Number 4: Pathogenesis of febrile nonhemolytic transfusion reactions

- Heddle NM, Klama L, Singer J, et al. The role of the plasma from platelet concentrates in transfusion reactions. *N Engl J Med* 1994;331:625-8.
- Do substances present in the plasma or the PLTs themselves cause the febrile nonhemolytic transfusion reactions (FNHTRs), often experienced by recipients of transfused allogeneic PLTs?
- approximately 30 percent of PLT transfusions had been shown to be associated with FNHTRs while 1% in RCC.
- The investigators observed 34 FNHTRs;
 - 20 with the infusion of the plasma component only
 - 6 with the cellular component only ($p = 0.009$)
 - 8 with the infusion of both components
- plasma component thus was found to be much more likely to cause a severe reaction than the infusion of PLTs ($p < 0.01$)

Number 4: Pathogenesis of febrile nonhemolytic transfusion reactions

- positive correlation was observed between the appearance of an FNHTR and the concentration of interleukin (IL)-1beta ($p < 0.001$) and IL-6 ($p = 0.034$) in the plasma transfused.
- removal of the plasma supernatant before transfusion or prestorage leukoreduction might minimize or prevent many FNHTRs

Number 5: Saline versus albumin for fluid resuscitation in critically ill patients

Finfer S, Bellomo R, Boyce N, et al. The comparison of albumin and saline for fluid resuscitation in the intensive care unit. *N Engl J Med* 2004;350:2247-56.

- a meta-analysis indicated that the use of albumin as a resuscitative fluid might be associated with increased mortality
- Recent meta-analysis on this topic evaluated 55 trials involving 2958 patients and showed no such effect
- large multicenter trial (n = 16), the SAFE study, based in Australia and New Zealand, evaluated 6997 hypovolemic critically ill patients who were randomly assigned to receive either albumin (n = 3497) or normal saline (n = 3500) during their resuscitation

Saline versus albumin for fluid resuscitation in critically ill patients

- primary outcome: any cause mortality over the 28-day study period
- the use of either albumin or normal saline for fluid resuscitation of critically ill patients resulted in similar outcomes at 28 days.
- data from subgroup analyses revealed that for trauma patients (n = 1186) albumin use was associated with a trend toward increased mortality.
- RCT raises the question, whether albumin should be used in patients for various non-evidence-based clinical indications

Number 6: The impact of receiving leukoreduced RBCs in patients undergoing cardiac surgery

- van de Watering LM, Hermans J, Houbiers JG, et al. Beneficial effects of leukocyte depletion of transfused blood on postoperative complications in patients undergoing cardiac surgery: a randomized clinical trial. *Circulation* 1998;97:562-8.
- patients for complex cardiac surgery were randomly allocated to receive non leukoreduced RBCs (n = 306); to receive prestorage leukoreduced RBCs (n = 305); or to receive bedside leukoreduced RBCs (n = 303)
- **primary outcome**: prevalence of postoperative infections.
- **Secondary outcomes**: in-hospital mortality and lengths of hospital stay
- **infection rates were higher in those who received non leukoreduced RCC than those who received either type of leukoreduced blood products (23.0% vs. 16.9% vs. 17.9%, respectively)**
- mortality was higher in the patients who had received non leukoreduced RCC
- investigators performed a second RCT, which confirmed the results of the first study
- leukoreduction significantly can reduce the risk of both mortality and postoperative infection after allogeneic RBC transfusion, at least in cardiac surgery patients

Number 7: The pathogen inactivation of PLTs

McCullough J, Vesole D, Benjamin RJ, et al. Therapeutic efficacy and safety of platelets treated with a photochemical process for pathogen inactivation. The SPRINT Trial. Blood 2004;104:1534-41.

- Novel synthetic psoralen, not found in nature (amotosalen), was used together with ultraviolet A (UVA) light
- RCT indicate that the use of pathogen-inactivated PLTs is not associated with increased bleeding.
- The pathogen inactivation (amotosalen and UVA) of PLTs is associated with reduced in vivo recovery and survival
- Provides the basis for a new paradigm in transfusion medicine: the pathogen inactivation of cellular blood products (PLTs and RBCs)

Number 8: The use of erythropoietin in critically ill patients

- Corwin HL, Gettinger A, Pearl RG, et al. Efficacy of recombinant human erythropoietin in critically ill patients: a randomized controlled trial. *JAMA* 2002;288:2827-35.
- Determine the efficacy of weekly recombinant human erythropoietin (rHuEPO) to decrease allogeneic RBC use in critically ill patients.
- Large (n = 1302) prospective, double-blind, placebo-controlled, multicenter trial conducted in 65 centers
- Patients receiving rHuEPO were less likely to undergo an allogeneic RBC transfusion (60.4% vs. 50.5%; $p < 0.001$).
- 19 percent reduction in the total of allogeneic RBC units transfused in the rHuEPO cohort
- Mortality was not significantly different in the two cohorts (14% for rHuEPO vs. 15% for placebo patients; $p = 0.61$)

Number 9: Preoperative autologous donation for hip replacement surgery

- Billote DB, Glisson SN, Green D, et al. A prospective, randomized study of preoperative autologous donation for hip replacement surgery. *J Bone Joint Surg Am* 2002;8:1299-304.
- usefulness of preoperative autologous blood donation (PAD) in reducing the need for allogeneic blood transfusions for patients undergoing elective hip replacement surgery
- patients randomized to the allogeneic cohort did not require any RBC transfusions whereas patients in the autologous cohort received a total of 42 autologous RBC units
- 34 of the 82 (41%) of the autologous units collected were not transfused
- **PAD provides no benefit for nonanemic patients undergoing elective primary hip replacement surgery**
- PAD significantly increases the likelihood for the use of an autologous transfusion, as well as the wastage of PAD units, contributing to increased cost of patient care in such patient

Number 10: The TRAP study

TRAP Study Group. Leukocyte reduction and ultraviolet B irradiation of platelets to prevent alloimmunization and refractoriness to platelet transfusions. *N Engl J Med* 1997;337:1861-9.

- Leukoreduction by filtration as well as UVB irradiation were effective in preventing alloimmune refractoriness after allogeneic PLT transfusion
- leukoreduced PLTs obtained by apheresis (from single donors) provided no incremental benefit to pools of leukoreduced whole blood–derived PRP PLT concentrates.

Outcome	Control	UVB	F-PC	F-AP	P1	P2	P3
Number of patients	131	130	137	132	NS†	NS	NS
Alloimmune and refractory	13%	5%	3%	4	0.03	0.004	0.01
Alloimmunized	45%	21%	18%	17	<0.001	<0.001	<0.001
Refractory	16%	10%	7%	8	0.17	0.03	0.06

* Control = nonleukoreduced (LR) pooled PRP PLTs; UVB = UVB-irradiated non-LR pooled PRP PLTs; F-PC = LR (by filtration) pooled PRP PLTs; F-AP = LR (by filtration) apheresis PLTs; PRP = whole-blood-derived PLTs manufactured by the PRP method; P1 = comparison of UVB vs. control PLTs; P2 = comparison of F-PC vs. control PLTs; P3 = comparison of F-AP vs. control PLTs.

† NS = not significant.

Cumulative meta-analysis of the eight RCTs that have examined the efficacy of leukoreduction in preventing HLA alloimmunization

Study (first author)	Publication year	Cumulative sample size (number per study)	Relative risk of HLA alloimmunization
Schiffer	1983	56 (56)	0.35 (0.10-0.60)
Sniecinski	1988	96 (40)	0.32 (0.17-0.60)
Andreu	1988	165 (69)	0.26 (0.16-0.49)
Kooy	1991	218 (53)	0.21 (0.12-0.35)
Oksanen	1991	249 (31)	0.23 (0.13-0.38)
Williamson	1994	372 (123)	0.27 (0.16-0.46)
Sintnicolas	1995	418 (46)	0.32 (0.18-0.56)
TRAP study [*]	1997	818 (400)	0.30 (0.20-0.46)

Differences in applicability of Evidence in transfusion medicine

- Policy decisions are based on a broader range of inputs.
- criteria for evaluating the efficacy and/or cost-effectiveness of proposed interventions differ from other areas.
- Reasons:
 - regulatory constraints
 - fear of future litigation
 - public perceptions of transfusion as being an inherently “unsafe” intervention
 - public expectations with regard to transfusion safety
 - proposals for applying the precautionary principle to transfusion medicine
- The precautionary principle: when a purported risk represents a threat of “serious or irreversible damage,” complete evidence of risk does not have to exist to institute measures to protect individuals and society from that risk.

Origins in the ruling of EC Court May 1998

Difference in applicability

- The “evidence- based” approach defers introduction of a measure for protecting the safety of the blood supply until definitive clinical or epidemiologic evidence of risk and/or benefit becomes available.

(rationale for introducing universal WBC reduction to prevent adverse TRIM effects)

- “Risk-management” approach favors the introduction of a precautionary measure that is designed to balance risk prevented by the implementation of the measure versus risk created by the introduction of the measure

(the risk-management approach would favor introduction of universal WBC reduction if the risk[s] of WBC reduction did not exceed the uncertain [or unproven] risk[s] of TRIM).

Where do we stand?

- Why we have not integrated EBM approach in theory and practice?
 - Medical curriculum not effective in teaching practice of EBM
 - No regulatory pressures
 - No institutional pressures because managers of health care not aware themselves
 - No medical, clinical audit culture
 - Uninformed and uneducated customers
 - Not enough incentives for practicing EBM
 - CPD credits system and its incorporation in service structure
 - It is an individual effort and maybe few private facilities have adopted this approach.
- Transfusion medicine is one of the most neglected field
- Policies are either not based on evidence or based on imported evidence

Why EB approach is urgently needed in transfusion medicine in our country?

- We have yet to restructure, organize and manage our national blood programme
- Our issues are not the same as those of developed countries so our policies and solutions cannot be same
- Local evidence is needed for our problems after identification of gaps in knowledge
- We are resource deficient country and can't afford to waste resources because of faulty policies that are based on either imported evidence or no evidence at all
- We have academic and moral responsibility to train our future generations

Where evidence is lacking in transfusion medicine in Pakistan

- **Transfusion service models – cost, effectiveness and sustainability**
 - What structures within each type of system are effective/ineffective in meeting supply and safety needs, and impacting on clinical outcomes in country?
 - What indicators can be used to compare equitability, effectiveness and sustainability of different systems?
 - What is the distribution policy in centralised systems?
 - What is the degree of inequity in access to blood supply in all systems?
 - What factors contribute to this inequity and what mechanisms can be used to improve existing hospital-based systems?
 - What is the true cost of blood to families in different systems (including hidden costs such as donor recruitment)?
 - How do hospitals make rational choices about transfusion recipients when supplies are inadequate?
 - What interventions can improve equitable access to blood?

Where evidence is lacking in transfusion medicine in Pakistan

- What is the full economic cost of 'donor vein' to 'recipient vein' blood, and associated pre-and post-vein activities, from different perspectives (e.g. health provider, recipients) in different systems?
- What attracts, motivates and retains professional transfusion staff?
- What career development structures are needed? What human resource skills are needed in the different systems?
- What educational methods should be used and how can they be evaluated?

Where evidence is lacking in transfusion medicine in Pakistan

■ Reducing transfusion-transmitted infections

- Can a centralised service be established to advise on validated test kits for TTIs?
- what robust, practical systems can be used to ensure test quality particularly in hospital based systems?
- Should malaria screening be carried out? Are there appropriate tools and what alternative strategies (e.g. treating recipients with antimalarials) more appropriate/cost-effective?
- Etc,etc,etc

Conclusions

- At present EBM is the best way to bring benefits of latest medical research to individual patient and has made patient care very objective.
- Over time the formal rules for evaluating evidence and strengths of different levels of evidence have been firmly established.
- EBM approach has been fully adopted in the field of Transfusion medicine in developed countries even though there are some caveats.
- We urgently need to adopt evidence based approach especially for policies applicable to transfusion medicine that can address our issues and prevents wastage of precious resources.
- Scientific community needs to take urgent steps to make progress in changing the present culture of practice of medicine.



THANK YOU