

## FEAMC Symposium

### The challenges of competence and compassion in Medicine

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#### Evidenced Based Medicine and Compassion

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The exercise of Medicine has a long history of scientific knowledge basis about the prevention, diagnosis, and treatment of human diseases. Since about fifty years ago (1967) a publication of a book by **Alvan Feinstein** - *Clinical Judgement*<sup>2</sup> called the attention on the role of the clinical daily common reasoning and clinical practices, and identified numerous factors of biases that could affect them to a negative way.

In 1972 **Archibald Leman Cochrane**, a Scottish epidemiologist, published another book - *Effective and Efficiency. Random Reflections on Health Service*<sup>3</sup> which described the lack of the controlled trials supporting many judges and clinical practices that had previously been assumed to be effective. Some other authors published textbooks and articles on clinical and epidemiological fields showing criticism and describing errors on physician reasoning and clinical decision-making. Toward the end of the decade of 1980 a group of cardiologists showed that a large proportion of performed invasive cardiologic procedures were considered inappropriate even by the standards of their own experts.<sup>4</sup>

The term “**Evidence-Based Medicine**” (EBM) was introduced later in 1990 by **Gordon Guyatt** of McMaster University (Hamilton, Canada) in the context of medical education as a new approach to the teaching, the practice and the exercise of Medicine.<sup>5</sup>

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<sup>2</sup> Alvan R. Feinstein. Clinical Judgment. William &Wilkins. 1967.

<sup>3</sup> Cochrane A. L. Effectiveness and Efficiency. Random Reflections on Health Services. Nuffield Provincial Hospitals Trust. 1972.

<sup>4</sup> Chassin M. R., Kosecoff J., Solomon D. H., Brook R. H. How coronary angiography is used: Clinical determinants of appropriateness. JAMA. 258 (18): 2443-47. 1987.

<sup>5</sup> Evidence-Based Medicine Working Group (November 1992). “Evidence-Based Medicine. A new approach to teaching the practice of Medicine. JAMA. 268 (17): 2420-25.1992.

Currently, the definition of EBM is “*the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. It means integrating personal clinical expertise with the best available clinical evidence from systematic research.*” The practitioner applies to the care of his patient (each one with personal characteristics, values, statutes and expectations) with his own individual clinical experience and the knowledge generally obtained on populations-based data, while absolutely respecting the fact that he has clinical expertise reflected in effective and efficient diagnosis and thoughtful identification and **compassionate** use of personal patients’ predicaments, rights and preferences.<sup>6</sup>

EBM methods involves the routine use of the scientific evidences obtained by clinical research in the treatment of the particular circumstances of a personal patient included in his familial and community involvement.

Evidence-based medicine exercise categorizes different types of clinical evidence and ranks them according to the strength of their freedom from the various biases that beset medical research:

1A – Evidences obtained by meta-analyses of several randomized control research (RCR) with double blind control.

1B - Evidences from only one randomized control research (RCR).

2A – Evidences from well-designed controlled research without randomization.

2B – Evidences obtained from well-designed cohort studies or case control studies, preferably from more than one centre or research group.

3 - Evidences obtained from multiple series designs and nonexperimental studies (comparative research, case studies) according to the textbooks. Dramatic and urgent results in uncontrolled trials.

4 – Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees. Evidences from experts and clinical practice.

So, following EBM rules, the foundation of any clinical decision regarding the optimal diagnostic or therapy procedure are scientific data resulting from clinical

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<sup>6</sup> Sackett D. L., Rosenberg W. M., Gray J. A., Haynes R. B. and Richardson W. S. Evidence based medicine: what it is and what it isn't, BMJ. 312 (7073): 71-72, 1996.

research. Clinical experience and intuition are a great help, but not the main tool in decision making. Indeed, making decisions about treatment of each individual patient is a complex process that allows doctors and patients to select the best possible solutions in one particular situation. The *EBM methods involves the routine use of the best scientific evidences obtained by clinical research in the treatment of the particular disease circumstances of a personal patient included in his familial, social and community involvement.*

This aim with the best scientific evidences was not possible before the existence of electronic data bases that occurred in the early 90,s. So, after this period it was possible the increasing acceptance of the concepts proposed initially by previously mentioned **Professor Archibald L. Ccchrane** by the systematic organization and intercommunication of electronic centers with evidence-based medical research data designated as **Cochrane Centers**, and a dedicated international organization - the **Cochrane Collaboration**. The explicit methodology to determine “*best evidence*” was largely established by the McMaster University Research Group.<sup>7</sup>

Today almost all western countries doctors apply EBM rules in the treatment for every patient with the support of the governments, institutions and scientific societies. This includes the recommendations to the use of practical guidelines referring to different diseases and the access to databases with the best scientific evidence from each category of procedure. Special experts edited guidelines which are continuously updated with new data coming from medical journals and the available literature with the last objective information.

A system for scientific evaluation the recommendations quality was developed in 2000 by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group. This system takes into account more dimensions then just the quality of medical research. It requires users who are performing an assessment of the quality of evidence, usually as a part of a systematic review about a particular subject, to consider the impact of different factors on their confidence in results. Authors of GRADE tables assign one of four levels to evaluate the quality of evidence on the basis of their confidence that the observed effect (a numeric value) is close to the true effect. The

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<sup>7</sup> Evidence-Based Medicine Working Group (November 1992). “Evidence-Based Medicine. A new approach to teaching the practice of Medicine. JAMA. 268 (17): 2420-25.

confidence value is based on judgements assigned in five different domains in a structural manner.<sup>8</sup> Systematic reviews may include since randomized controlled trials, that have low risk of bias, to observational studies that have high risk of bias. In the case of randomized controlled trials, the quality of evidence is high but can be downgraded in multiple domains. In guidelines, recommendations for a clinical service are classified by the balance of risk versus benefit and the level of evidence on which this information is based. The U.S. Preventive Services Task Force uses the following system:<sup>9</sup>

. Level A: Good scientific evidence suggests that the benefits of the clinical service substantially outweigh the potential risks: Clinicians should discuss the service with eligible patients.

. Level B: At least fair scientific evidence suggests that the benefits of the clinical service outweigh the potential risks. Clinicians should discuss the service with eligible patients.

. Level C: At least fair scientific evidence suggests that the clinical service provides benefits, but the balance between benefits and risks is too close for general recommendations. Clinicians need not offer it unless individual considerations apply.

. Level D: At least fair scientific evidence suggests that the risks of the clinical service outweigh potential benefits. Clinicians should not routinely offer the service to asymptomatic patients.

. Level I: Scientific evidence is lacking, of poor quality, or conflicting, such as the risk versus benefit balance cannot be assessed. Clinicians should help patients understand the uncertainty surrounding the clinical service at this category.

The Cochrane Library is a collection of databases in medicine and other health care matters provided by Cochrane Collaboration (CC) and other organisations. The CC is an international not-for-profit independent organisation dedicated to making up-to-date accurate information about the effects of healthcare reality worldwide available. It produces and disseminates systematic reviews of healthcare interventions and promotes the source of evidence in the form of clinical trials and other studies. The Cochrane

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<sup>8</sup> GRADE guidelines: 3. Rating the quality of evidence. Balshem H., Helfand M., Schunemann H. J., et al. *Journal of Clin. Epidemiol.* 64 (4): 401-6. 2012.

<sup>9</sup> Sherman M., Burak K., Maroun J. et al. Multidisciplinary Canadian Consensus Recommendation for the Management and Treatment of Hepatocellular Carcinoma. *Current Oncology.* 18 (5): 228-40. 2012.

Collaboration was founded in 1993 and named after the British epidemiologist. It publishes the Cochrane Database of Systematic Reviews which is published quarterly as part of the Cochrane Library. At its core is the collection of Cochrane Reviews, a database of systematic reviews and meta-analyses which summarizes and interprets the results of high-quality medical research. It permits to make the results of well-conducted controlled trials readily available and is a key resource in EBM. It consists of a regularly updated collection of EBM databases:<sup>10</sup>

- . The Cochrane Databases of Systematic Reviews (Cochrane Reviews)
- . The Database of Abstracts of Reviews of Effects (DARE)
- . The Cochrane Central Register of Controlled Trials (CENTRAL)
- . The Cochrane Database of Methodology Reviews (Methodology Reviews)
- . The Cochrane Methodology Register (Methodology Register)
- . Health Technology Assessment Database (HTA)
- . NHS Economic Evaluation Database (NHS EED)

The dedicated guideline panelists may make strong or weak recommendations on the basis of further criteria. The most important criteria are the balance between the desirable and undesirable effects not considering the costs, the quality of the evidence, values and preferences of the patients, and finally the costs related to the available resources utilization.

The Group for Evidence Based Medicine Resource from McMaster University identified the approach to the application that each individual physician must follow in five steps: <sup>11</sup>

1- Problem definition: Patient/problem (what kind a problem to find solutions: (diagnosis, procedures, interventions...)).

2 – Selection of wanted sources of information.

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<sup>10</sup> Sackett D. L., Richardson W. S., Rosenberg W. S., Haynes R. B. Evidence based medicine. How to practice and teach. 2nd edition. Churchill-Livingstone. Edinbourg. 2009.

<sup>11</sup> Silverman W. A. Where is the evidence. Debates on modern medicine. Oxford University Press. Oxford. 1996.

3 - Critical evaluation of the information.

4 - Application of information to the patient/situation.

5 – Efficacy evaluation of the application on the patient.

Evidence based medicine (EBM) is a conscious and reasonable method of use of contemporary best evidence in making adequate decisions about the treatment of individual patients. It is not a medical cook-book with recipes, but its good application brings cost-effective and better health care, permitting the most convenient and the best possible evidence for the physician solutions to his patient's disease problems. It helps to avoid major mistakes in the treatment evolution and raises the global quality of health care. Of course, EBM requires knowledge of the physician in working on the computer which will permit the access to the medical databases, to the medical literature, and the capacity to a correct interpretation of statistical and epidemiological results. In present times it is an excellent instrument together with clinical physician expertise for the treatments of the patients.

So, making use of the best instruments that the contemporary time of life has offered to our daily tasks as physicians, we need to involve our service to the vulnerability, fragility and suffering of the individual patients with the absolute necessary interest, attention, solicitude and fraternity. It means we must involve the care to the patients with the referred physician characteristics of ***Individual Clinical Expertise, Best External Evidence and attention to the Patient Values and Expectations*** with the ***Blessing of the Compassion***.

Let us remember the message of His Holiness Pope Francis at the recent occasion of thirtieth World Day of the Sick. *“Let us thank the Lord for the progress that medical science has made, especially in recent times; new technologies have made it possible to prepare therapies that are a great benefit to the sick; research continues to make a valuable contribution to eliminating old and new pathologies; rehabilitation medicine has greatly expanded its expertise and skills; none of this, however must make us forget the uniqueness of each patient, his or her dignity and frailties. Patients are always more important than they their diseases, and, for this reason no therapeutic can prescind from listening to the patient's his or her history, anxieties and fears. Even when healing is not possible, care can always been given. It is always possible to console, it is always possible to make people sense a closeness that is more interested in the person than on his or her*

*pathology. For this reason, I would hope that the training provided to health care workers might enable them to develop a capacity for listening and relating to others.*<sup>12</sup>

We were convoked to this meeting from most countries in Europe from Christian Church as Catholic Physicians to reflect, to dialog, and to pray together about the theme “*Challenges of Competence and Compassion in Medicine*”. In these synodal times of the Church we participate with our ideas based in our daily work and tasks in our different countries, with our presence as a contribution to the synodal works, with the debate of ideas, the dialogs and testimonies. As pilgrims in this wonderful Sanctuary of Assisi in a time of suffering and misery we feel that where abounds suffering superabounds the Grace of Spirit, referring the letter of Saint Paul to the Romans.<sup>13</sup>

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<sup>12</sup> Message of His Holiness Pope Francis at occasion of thirtieth World Day of the Sick.

<sup>13</sup> Romans, 8:22.