Evidence Based Medicine Werner Vosloo ND

"It's about integrating individual clinical expertise and the best external evidence"

"Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice."

Evidence based medicine and the evidence based practice is a hot topic for clinicians and just about everyone with a vested interest in the medical industry.

It has been extensively written about in the last few decades, with currently in January 2016, 115774 articles listed in PubMed with search words "Evidence based medicine".

David Sackett (November 17, 1934 – May 13, 2015) has authored numerous insightful articles on this topic and is considered one of the fathers of modern day evidence based medicine and clinical epidemiology.

Evidence based medicine relies on:

- 1. patient centered clinical research into the accuracy and precision of diagnostic tests (including the clinical examination),
- 2. the power of prognostic markers,
- 3. and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens.

Seven steps in the implementation of evidence based medicine:

Step Zero: Cultivate a spirit of inquiry.

This pivotal step is the starting point – cultivate the mind that asks the questions.

Step 1: Ask clinical questions in the efficient PICOT format.

Inquiries in this format take into account patient Population of interest (P), Intervention or area of interest (I), Comparison intervention or group (C), Outcome (O), and Time (T).

Step 2: Search for the best evidence.

This typically means studies in research databases such as PUBMED or MEDLINE, using accurate keyword searches.

Step 3: Critically appraise the evidence.

The following questions can help:

Methods: is the study well designed and executed, with sound methodology for area of investigation?

Was the inclusion and exclusion criteria mentioned?

Was the search strategy stated?

Was the validity of the studies included assessed?

Was an estimate of the effect of each subgroup studied summarized?

Was the review up to date?

Are the results of the study valid? What are the results and are they important? Will the results help me care for my patients?

<u>Step 4:</u> Integrate the evidence with clinical expertise and patient preferences and values. Clinical expertise, based on patient assessments, laboratory data, and data from outcomes management programs, as well as patients' preferences and values are important components of evidence based medicine.

<u>Step 5:</u> Evaluate the outcomes of the practice decisions or changes based on evidence. Data collection is required to monitor and evaluate any changes in outcomes so that positive effects can be supported and negative outcomes evaluated and improved upon.

Step 6: Disseminate results.

This improves the practice of medicine, sharing your breakthroughs through dissemination in appropriate publications.

The bottom up approach in true evidence based medicine prevents misuse as cookbook medicine, as it by definition takes into account patient preference, individual clinicians expertise and current best evidence within area of focus.

Cost of care delivery and allocation of "scarce" resources are also of significant consideration to enable a health care system to be sustainable, as doctors searching for the most efficacious treatments for their patients may increase the cost of care delivery.

The above tenets help to prevent misuse, especially in a free choice open market medical system, administrators, purchasers, investors and others with an interest in making medicine more efficient and less costly to deliver with anything less than patient health outcomes as objective.

As a physician in private practice, evidence based medicine starts at devoting research and reading time to "selective, efficient, patient driven searching, appraisal, and incorporation of the best available evidence". 1

Evidence based change in medical paradigm:

A historical example of implementation of a valuable and lasting change, saving countless lives – Ignaz Semmelweis.

In mid 19th century Vienna, Dr. Semmelweis was in charge of two obstetric clinics, with very different mortality rates.

Clinic 1 was a training hospital for physicians, Clinic 2 for training midwives. Respective mortality rates of puerperal fever for the time period 1841-1846 was 10% and 4%. The physicians clinic lost more than double the amount of patients to Streptococcus pyogenes infections, the cause of puerperal or childbed fever as compared to their midwife counterparts.

This was before the time Pasteur with the germ theory of disease and Lister's contribution to using carbolic acid to sterilize instruments used in surgical medicine. The causation of puerperal fever was still a mystery.^{2,4,6,9}

Dr. Semmelweis was deeply affected by the difference in maternal mortality rates. It was obvious to him that, in the same population and geographic area the two clinics served, the difference was in the manner the clinics functioned. He demonstrates the most crucial part of evidence based medicine:patient centered observation and a spirit of inquiry and tirelessly searched for answers for years.

Only when a colleague and friend, Jakob Kolletschka died after being nicked with a scalpel during a post mortem exam, did he find the evidence he needed to make his breakthrough.

The maternity patients contracting puerperal fever had a very similar disease presentation to the late Kolletschka, with lymphangitis, peritonitis, pericarditis, pleurisy, meningitis, and metastases of foci of infection containing pus.

The similarity between the circumstances of contracting the illness through contact with a cadaver, development of symptoms, disease progression and eventually death was similar. This led Semmelweis to considering physicians being the vector that transfers the disease causing agent from corpses to patients in the maternity ward.^{5,6}

In Clinic 1, where the doctors trained, physicians would do postmortems on the maternity patients that died the previous night from puerperal fever and then transition to do exams and deliveries with soap washed or sometimes unwashed hands, literally carrying Strep or "cadaveric contamination" to the patients in labor, with a recorded maternal mortality rate of 90.2 per 1,000 deliveries (1,989 total maternal deaths out of 20,204 total deliveries) for Clinic 1 for the time period 1839-1847. In the same time period, the recorded maternal mortality rate was 33.8 per 1,000 deliveries (691 total maternal deaths per 17,791 deliveries) where no postmortems were done by the midwifery students in Clinic 2.4

The smell of the examiners hands after autopsies and dissections convinced Semmelweis that the decaying organic matter thought to transmit puerperal fever was still present. Semmelweis implemented hand washing with calcium hypochlorite until the putrid smell of the autopsies was no longer detectable on the dissectors hands. Subsequently the mortality rate was reduced by 90%, from 18.3% in 1847 to 3.5%, a decrease approximating the second clinic where the midwives did not do post mortem exams in between deliveries. While removing the odor of decay, chlorine also removed the disease causing agent, Group A hemolytic streptococcus, unknown at that time. In 1847, in the Vienna General Hospital, Semmelweis implemented hand washing for interns who had performed autopsies with calcium hypochlorite, with resultant reduction in the maternal mortality rate from childbed fever from 10% to 1-2%.

Semmelweis wrote a 500 page report of his findings "The Etiology, Concept, and Prophylaxis of Childbed Fever" which was published initially in 1861. Kay Codell Carter, who translated the original German text into English in 1983, remarks that in addition to clearly presenting his findings, he dedicates much of the manuscript to attacking his critics. Carter concludes that this contributed to the global non-acceptance of sterilization techniques in medicine of the 1860's.⁹

Evidence based change occurred with resultant improvement in medicine.

The two main factors determining the acceptance or rejection of ideas are the time of introduction and the nature of the professional audience.⁵

Dr. Semmelweis was initially ridiculed and rejected for introducing sterile technique, eventually dying in exile in reportedly a mental asylum.

Timing was not optimal and the professionals at the time chose to ignore the clear evidence that physicians could transfer disease from one patient to another. In contrast, Dr. Egas Moniz pioneered and introduced frontal lobotomy in 1936 for incurable mental illness and received a nobel prize in 1949. The time and audience was right.⁵

Lister, who introduced sterilization, and Pasteur, known for the germ theory of disease, would eventually be credited with what should initially have been Semmelweis's recognition.

Now, 200 years after his birth we honor him as an outstanding example of a practitioner of evidence based medicine saving many lives with his contribution.

As we enter an era of potential universal health insurance in a centralized single payer system, I raise the question and concern that there will be an emphasis on numbers and statistics, to the neglect of patient preference and physician clinical judgement and experience in the practice of medicine.

- 1. Sackett DL et al. (1996). "Evidence based medicine: what it is and what it isn't". BMJ 312 (7023): 71–2
- 2. Medicine in stamps-Ignaz Semmelweis and Puerperal Fever, Ahmet Dogan Ataman et al. J Turk Ger Gynecol Assoc. 2013
- 3. Evidence based medicine: a movement in crisis? Trisha Greenhalgh et al. BMJ. 2014; 348: g3725.
- 4. Ignaz Phillip Semmelweis' studies of death in childbirth. Loudon I (2013). JLL Bulletin: Commentaries on the history of treatment evaluation
- 5. Innovation in medicine: Ignaz the reviled and Egas the regaled. <u>Csoka</u>. Med Health Care Philos. 2015 Dec 14.
- 6. The Semmelweis reasoning and the puerperal fever. Sabbatani S Infez Med. 2008 Mar;16(1):47-58.
- 7. Evidence-Based Practice: Step by Step: The Seven Steps of Evidence-Based Practice Melnyk et al. AJN, American Journal of Nursing: January 2010 Volume 110 Issue 1 pp 51-53
- 8. Evidence-based medicine between explicit rationing, medical deontology and rights of patients. Frati, P et al. 1998 Oct-Dec;8(4):383-94.
- 9. The Etiology, Concept, and Prophylaxis of Childbed Fever by Ignaz Semmelweis 1861. Translated by Kay Codell Carter 1983
- 10. Evidence-based medicine: a new ritual in medical teaching. Sinclair British Medical Bulletin June 2004