EBM in primary health care

張必正 *MD, MSc*
張必正家庭醫師診所院長
中華民國醫師公會全聯會副秘書長
世界家庭醫師組織WONCA亞太區秘書長

What Is EBM

- Evidence based medicine is the conscientious, judicious and explicit use of current best evidence in making decisions about the care of individual patients. (Dave Sackett, 1996, BMJ)
- EBM is a tool for quality improvement in primary care and 'the use of mathematical estimates of the chance of benefit and the risk of harm, derived from high-quality research on population samples, to inform clinical decision-making" (Greenhalgh T, Donald A , 2002)

實證醫學的精神 "3 E"

5 steps of EBM

- Formulation of a clinical question
- Search of the literature for the best available evidence
- Critical appraisal of the evidence
- Application of the evidence in clinical practice
- Evaluation of performance

Clinical guidelines and evidence based medicine, 2003

Is EBM appropriate in PHC?

- Lack of training and attitude toward EBM
- Educators in medicine are not equipped or motivated to incorporate EBM into their clinical teaching
- Concerns about whether evidence exists to answer specific questions
- Excessive emphasis placed on it can lead to conflicts with a clinician's duty of care and respect for patient autonomy
- Guidelines synthesize all the evidence and help shift practice and points to changes in practice in response to evidence as leading to the recent reduction in cardiovascular deaths *(Vause, 2012)*

Citation: Edirne T (2012) Is Evidence-Based Medicine Appropriate in Primary Care? Primary Health Care 2:e108. doi:10.4172/2167-1079.1000e108

Is EBM appropriate in PHC?

- Others point that guidelines are a very imprecise tool, often including evidence that is poor quality or irrelevant and overly prescriptive for the complex contexts of primary care. (Mangin, 2012)
- Clinical decisions need to take into account many more factors than the ones presented in a linear flowchart
- Difficulties in finding relevant evidence to a specific patient with particular set of conditions, beliefs, expectations and social situation.

基層醫療與EBM

- 健保審查
- 糖尿病ADA guidelines
- 血壓控制 JNC guidelines
- 血脂控制 Improve it study
- Fixed dose combination
- 醫療糾紛

健保審查

- metformin, 2nd line DM medications
- Statin
- Urate Lowering Therapy

Question remains:
Is it for evidenced practice, or for cost saving?

糖尿病(2017 ADA)

Table 1—ADA evidence-grading system for "Standards of Medical Care in Diabetes"

Level of evidence	Description
A	Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered, including • Evidence from a well-conducted multicenter trial • Evidence from a meta-analysis that incorporated quality ratings in the analysis Compelling nonexperimental evidence, i.e., "all or none" rule developed by the Centre for Evidence-Based Medicine at the University of Oxford Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including • Evidence from a well-conducted trial at one or more institutions • Evidence from a meta-analysis that incorporated quality ratings in the analysis
B	Supportive evidence from well-conducted cohort studies • Evidence from a well-conducted prospective cohort study or registry • Evidence from a well-conducted meta-analysis of cohort studies Supportive evidence from a well-conducted case-control study
C	Supportive evidence from poorly controlled or uncontrolled studies • Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results • Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls) • Evidence from case series or case reports Conflicting evidence with the weight of evidence supporting the recommendation
E	Expert consensus or clinical experience

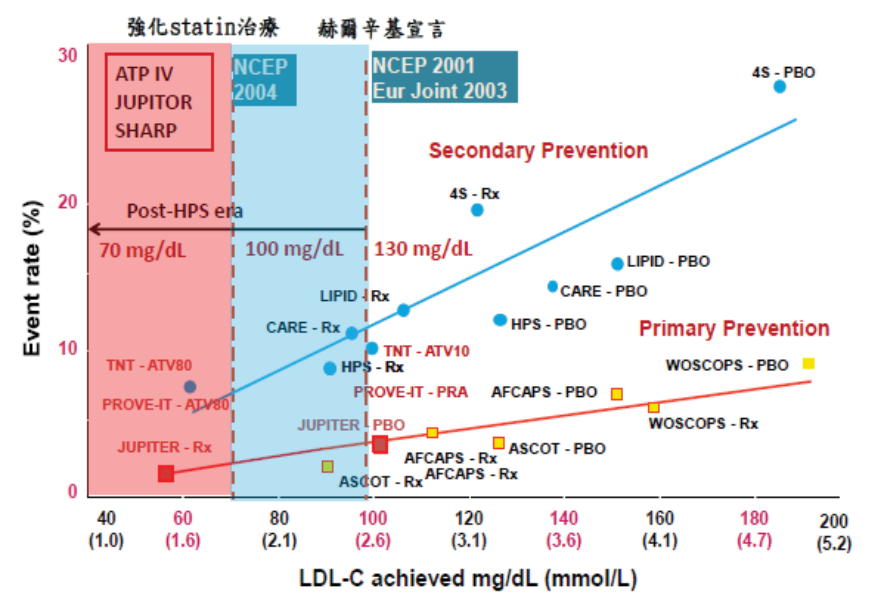
血壓控制JNC8

表一、建議強度表

等級	建議強度
A	強烈建議 有高度證據證實可以得到大幅的淨利 (net benefit)[a]。
B	中度建議 有中度證據證實可以得到中度的淨利。
C	薄弱建議 至少有中度證據證實可以得到小幅的淨利。
D	不建議 至少有中度證據證實沒有淨利，或者其風險或傷害大於好處。
E	專家意見 沒有證據、證據不足或不明確、或者證據間相互衝突，所以好處與傷害之間的平衡並未確定，因此淨利並不明確。 但專家認為提供臨床指引和給予建議是重要的，應在這領域進行後續研究。
N	沒有建議或反對 因為沒有證據、證據不足或不明確、或證據間相互衝突，所以好處與傷害之間的平衡並未確定，因此淨利並不明確。 專家認為不應該給予建議，應在這領域進行後續研究。

[a] 淨利 (net benefit)：定義為服務 / 介入的好處減掉其產生的風險或傷害。

Even lower, even better: lipid lowering on CV events



10-year milestone of lipid lowering target

1994: **Scandinavian Simvastatin Survival Study (4S)**

LDL-C: **190** ➔ **124**

Lancet. 1994 Nov 19;344(8934):1383-9.

2004: **PROVE-IT** TIMI22

LDL-C: **95** ➔ **62**

N Engl J Med. 2004 Apr 8;350(15):1495-504.

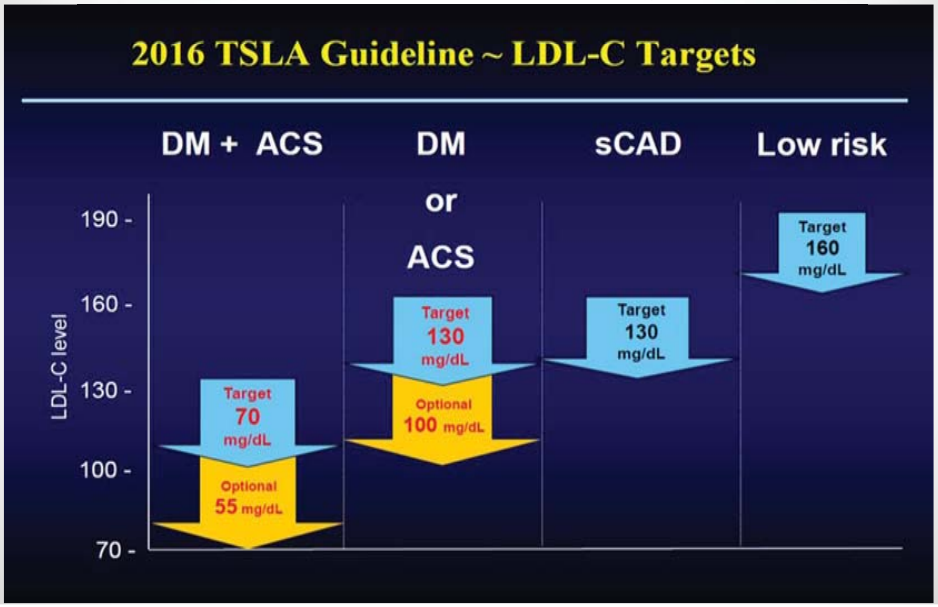
2014: **IMPROVE-IT** TIMI40

LDL-C: **69** ➔ **53**

N Engl J Med. 2015 Jun 18;372(25):2387-97.

Evidence keeps changing

台灣本土血脂治療指引

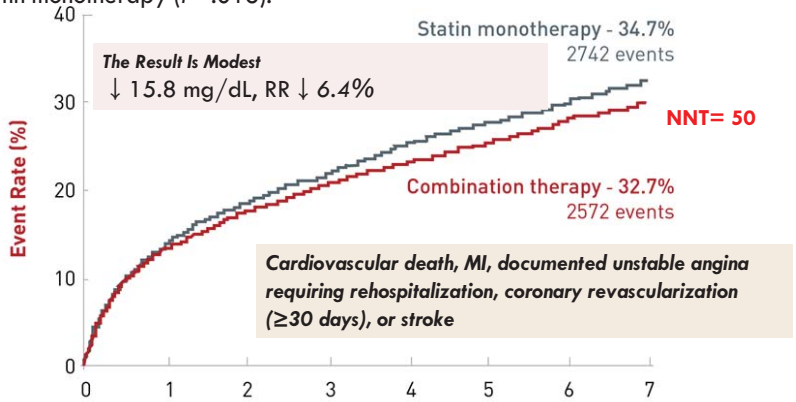


Fixed dose combination therapy

- Advantages *(Circulatioin, 2010)*
  - Compliance
  - Reduced cost of therapy
  - Increase the ease of prescribing
  - Avoid multiple steps for dose titration of each drug
- Uncertainties
  - Clinical outcome unknown
  - Adverse effect on long term treatment
  - Long term safety in primary prevention

Primary Endpoint — ITT

The intention-to-treat analysis of IMPROVE-IT showed that the primary endpoint occurred in 32.7% of patients assigned ezetimibe/simvastatin vs. 34.7% assigned simvastatin monotherapy (*P*=.016).



Better outcome in fixed dose combo

7-year event rates. Statin monotherapy: simvastatin 40 mg. Combination therapy: ezetimibe/simvastatin 10 / 40 mg.
Primary endpoint: Cardiovascular death, MI, documented unstable angina requiring rehospitalization, coronary revascularization (≥30 days), or stroke.

實證醫學 vs. 醫療糾紛

案例一

- **案例事實**
  - 柳○○於93年6月16日在庚診所健檢結果，其腹部超音波顯示有輕度脂肪肝，肝臟右葉有一個0.6公分的囊腫。
  - 柳○○於94年5月16日契約屆滿時尚未及續約時，即於94年6月9日發生劇烈腹痛，並於同年月11日前往辛醫院，始發覺罹患慢性B型病毒性肝炎肝癌。
  - 於95年2月15日因肝癌死亡。

台北地方法院96年度醫訴字第10號、高等法院97年度醫上訴字第6號刑事判決。

案例一

- **案例事實**
  - 被告乙為外科醫師，經營庚診所並擔任院長職務，柳○○自91年間1月起至94年5月16日連續三年期間，均為庚診所之會員，每年度繳交會員費用後，安排一次制式健康檢查。
  - 被告乙據庚診所之健檢報告及柳○○於加入庚診所會員時所填具之「健康檢查身體狀況問卷表」，知悉柳○○為B型肝炎帶原者。

台北地方法院96年度醫訴字第10號、高等法院97年度醫上訴字第6號刑事判決。

案例一

- **本案爭點**
  - 被告乙○○是否有未盡注意義務提供必要之醫療檢查，讓被害人及家屬造成無可回復之損害？

台北地方法院96年度醫訴字第10號、高等法院97年度醫上訴字第6號刑事判決。

Physicians vs. Legal Profession Viewpoints:

Taiwan's study … a preliminary report

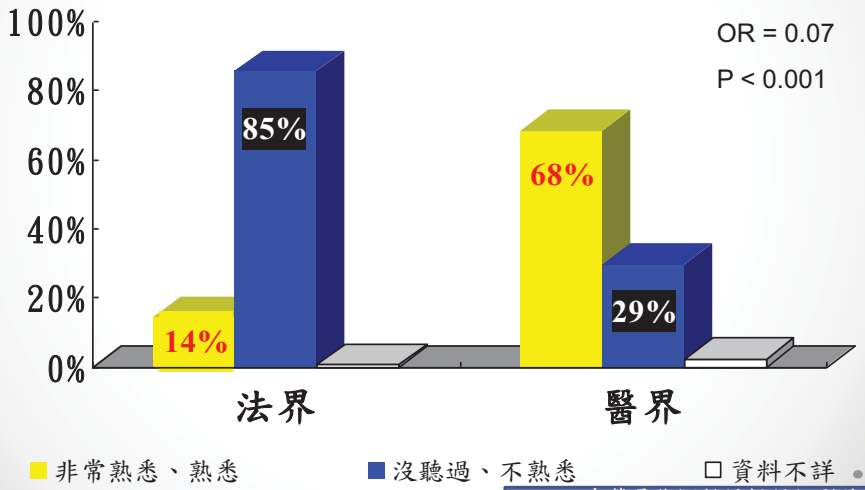
中榮吳俊穎教授提供投影片

鑑定報告書引用之文獻

- 醫審會鑑定報告書
  - 大多數完全引用國外文獻
  - 多半未針對是否適用於該特定個案而討論
  - 幾乎沒有區分文獻的證據等級

中榮吳俊穎教授提供投影片

對於實證醫學的熟悉度

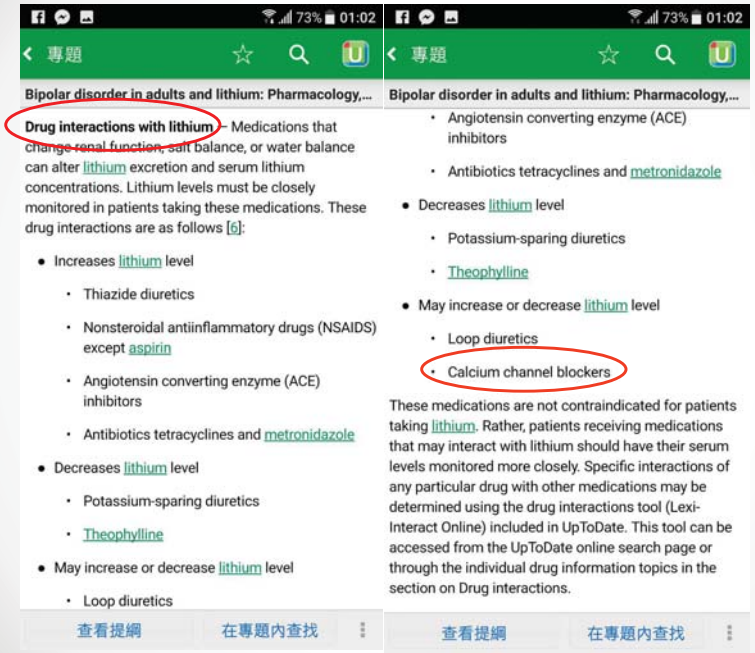


中榮吳俊穎教授提供投影片

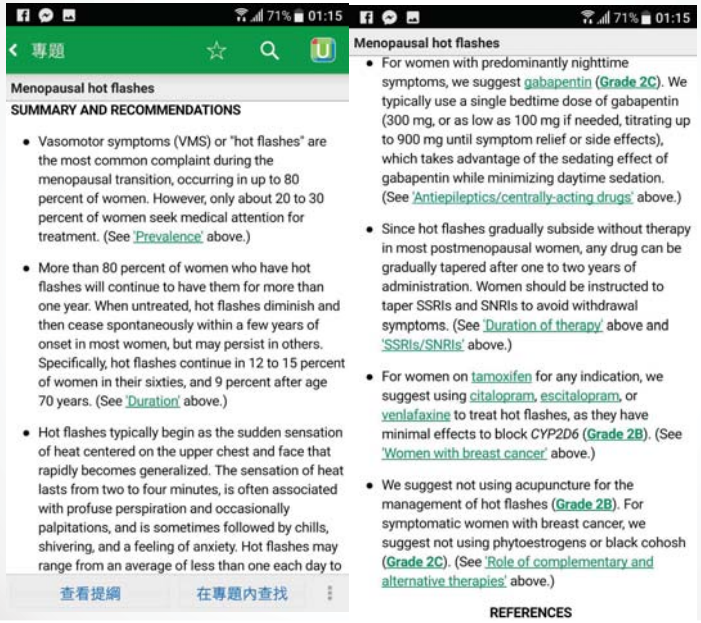
EBM and CPG in trials

- **EBM methodology as a tool in trials?**
- **CPG as standards of care?**
  - **If yes, exculpatory or inculpatory?**

UpToDate



Summary and recommendations



Conclusion

To handle the complexity of medicine without loosing the meaning of complexity of illness in the context of relationships is crucial.

Patients' and physicians' feelings and emotions as well as the affection between physician and patient should not be neglected.

Evidence-based medicine should help us to present the information, the risks to the patient and outline our treatment options and to be able to go on with saying "*Mr. B*, based on this information and our discussions, how do you feel about all of this and what would you wish to do?"