WEEKLY EPIDEMIOLOGICAL REPORT

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Evidence-Based Medicine (Part II)

This is the second in a series of two articles on Evidence-Based medicine (EBM)

Practical examples of EBM

EBM is not a purely academic or financial exercise and its implementation has major clinical implications.

Single studies: Management of fever in children (evidence level 1+)

Fever is common in the under fives and although usually benign, may occasionally cause convulsions. This risk, combined with the desire to alleviate symptoms in infants, has led to widespread use of paracetamol or ibuprofen as antipyretics. Current NICE guidelines state that either approach is effective.

However, many parents will also use a combination of both agents, in the belief that this will enhance speed of resolution. Is this belief based in reality?

A UK primary care-based study randomized 156 children aged between six months and six years to receive either paracetamol alone, ibuprofen alone or a combination, as treatment for pyrexia (37.8–41.0 °C) in the presence of otitis media managed at home. Treatment was given for the first 24 hours to all patients and for the subsequent 24 hours if symptoms demanded. Randomization was by automated system and blinding was maintained using a double-blind approach.

The primary outcome was a comparison of the mean time without fever in the first four hours. Children taking paracetamol alone had significantly less time free of fever than those on combination therapy ($p<0.001$). There was no significant difference between those taking ibuprofen alone and those on combination therapy ($p=0.2$). Secondary outcomes included 24 and 48hour assessments, as well as mean temperature, time to first temperature relief and a range of patient-related outcomes. These all showed the same qualitative trend, with combination therapy being significantly better than paracetamol alone, but generally showing non-significant benefits versus ibuprofen alone. Ibuprofen alone was also significantly better than paracetamol alone for both primary outcome and most secondary outcomes.

This study gives practical information for primary care – suggesting that combination therapy offers advantages over paracetamol alone, although probably not over ibuprofen.

Systematic reviews: Heparin in venous thromboembolic disease (evidence level 1++)

Deep vein thrombosis (DVT) and pulmonary embolism (PE) are major causes of death and disability. Overall, clinically recognized DVT and/or PE occurs in about 0.5 persons per 1,000 each year, although rates in the elderly are approximately four times this figure. Exposure to specific risk factors such as immobilization, lower limb injury, surgery and acute severe infections results in a dramatic increase in risk.

The use of heparin underlies both prevention and treatment of DVT/PE, with treatment protocols having been examined in a bewilderingly large range of RCTs. However, the study quality is variable and makes the identification of the optimum treatment something of a challenge. This is an ideal field for the use of systematic review and meta-analysis, provided that these have been carried out under high standards – the ideal source for this level of data is the Cochrane Collaboration, which applies a consistent

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valid protocol to all reviews published under its auspices. There are many Cochrane reviews in the field of thrombo-embolic disease, each addressing a single explicit clinical question. Areas addressed include: What is the best strategy for preventing DVT in high-risk situations? What is the best treatment for established thrombo-embolic disease? Is treatment best given in a hospital or home environment? All reviews give details on protocol, search strategy, included and excluded studies and quality appraisal narratives for all studies. Comprehensive results are given for both individual studies and the pooled results of the meta analyses to inform the decision making process.

By working through the various reviews, we can ascertain that:

- Prophylactic treatment with heparin reduces occurrence of DVT in high-risk patients.
- Use of low molecular weight heparin(LMWH) in patients with established thrombo-embolic disease is associated with fewer thrombotic complications, lower mortality and a lower risk of haemorrhage.
- Use of LMWH at home is associated with better outcomes and fewer serious adverse effects than either unfractionated heparin or LMWH used in hospital.
- Twice-daily dosage is preferable to once daily

This approach exemplifies how complex questions that are not amenable to single study answers can be addressed using well designed systematic reviews utilizing a standardized methodology

Non-randomised studies: Influenza vaccination in over-65 years (evidence level 2++)

Current UK guidance mandates routine influenza vaccination for all patients aged 65 years and over, in addition to those younger patients with diabetes, immune suppression or various forms of chronic pulmonary, cardiovascular, renal and liver disease. Although the majority of those aged over 65 are vaccinated, achievement of adequate vaccination in younger at-risk patients is substantially lower. The evidence that improving vaccine coverage is worthwhile is mixed. In the Netherlands, where an intensive national strategy achieved vaccination rates of 80% in the 1990s, a 20% reduction in influenza related mortality in the elderly was seen. In the USA, however, no such benefit has been detected in retrospective studies. The problem when assessing the benefit of any vaccination strategy is that RCTs are difficult to carry out in this context.

Mortality is rare, even among high-risk groups, so very large sample sizes are required. Demonstration of benefit depends on the circulating virus matching the type contained in the vaccine, a requirement that cannot be relied on in advance

The administration of a placebo to at-risk patients may well be considered unethical. For this reason, we must depend on the results of case-control studies or cohort analyses, study types that are inherently more prone to bias because of the presence of confounding clinical features. A systematic review of studies assessing vaccine effectiveness showed that the presence of confounders resulted in anything between a 220%underestimate to a 21% overestimate of influenza vaccine effectiveness.

Any assessment of vaccine benefit must, therefore, take very careful account of these factors.

A retrospective cohort study from the USA reviewed the impact of influenza vaccination in those aged over 65 years in five US states. A total of 713,872 patient-years were available for analysis, with an overall vaccination rate of around 58%. Common confounders such as age, gender, co-existing medical conditions and prior use of health care facilities were taken into account when calculating the results. Vaccination appeared to reduce the risk of hospitalization for influenza or pneumonia by 27% and the seasonal all-cause mortality rate by 48%. A particular strength of this analysis is that the authors then went on to explore what the impact on these results would have been if there had been an unsuspected confounder. The results show that even if a powerful confounder had been present, resulting in a threefold increase in risk and present in 60% of patients, substantial mortality benefit would remain. This study exemplifies how, in the absence of RCTs, careful use and interpretation of non-randomized studies can nonetheless yield results of clinical significance.

Conclusion

In the 15years since EBM first emerged as a coherent approach to assessing treatment options, we have seen its adoption, alongside health economics, as the gold standard tool for commissioning and provision of health services around the world. It is being applied not only to pharmaceutical treatments but also increasingly to surgical interventions, diagnostic tests and medical devices.

Additionally, improved access to resources and integration with medical IT systems means that clinicians are now, more than ever, in a position to implement evidence at the point of contact with individual patients, ensuring that evidence is translated into practice.

Perhaps the area where work remains to be done is in the effective communication of the EBM message to patients. There is still a perception – often fuelled by an ill-informed media–that decisions to restrict treatments are always purely financial in nature. While this may well be the case in some circumstances, the removal of ineffective or potentially harmful treatments should serve to enhance the quality of healthcare: communicating this perspective will represent the next challenge for EBM.

Compiled by Dr Madhava Gunasekera of the Epidemiology Unit

Source

What is evidence-based medicine? available from
www.medicine.ox.ac.uk/bandolier/painres/download/whatis/ebm.pdf

Table 1: Vaccine-preventable Diseases & AFP

01st – 07th September 2012 (36thWeek)

Disease	No. of Cases by Province									Number of cases during current week in 2012	Number of cases during same week in 2011	Total number of cases to date in 2012	Total number of cases to date in 2011	Difference between the number of cases to date in 2012 & 2011
	W	C	S	N	E	NW	NC	U	Sab					
Acute Flaccid Paralysis	01	00	00	00	00	00	00	00	00	01	00	55	62	- 11.3 %
Diphtheria	00	00	00	00	00	00	00	00	00	-	-	-	-	-
Measles	00	01	00	00	00	00	00	00	00	01	00	42	104	- 59.6 %
Tetanus	00	00	00	00	00	00	00	00	00	00	01	08	17	- 52.9 %
Whooping Cough	01	00	01	00	00	00	00	00	00	02	03	69	25	+ 176.0 %
Tuberculosis	06	00	00	04	00	05	00	05	02	22	244	6107	6401	- 04.6 %

Table 2: Newly Introduced Notifiable Disease

01st – 07th September 2012 (36thWeek)

Disease	No. of Cases by Province									Number of cases during current week in 2012	Number of cases during same week in 2011	Total number of cases to date in 2012	Total number of cases to date in 2011	Difference between the number of cases to date in 2012 & 2011
	W	C	S	N	E	NW	NC	U	Sab					
Chickenpox	12	06	05	03	04	05	03	05	05	48	26	3205	3042	+ 05.3 %
Meningitis	04 CB=1 GM=2 KL=1	01 KD=1	00	01 VU=1	01 TR=1	03 KR=2 PT=1	01 AP=1	00	05 KG=2 RP=3	16	12	550	615	- 10.6 %
Mumps	17	06	09	03	05	12	04	04	16	76	34	3466	2237	+ 54.9 %
Leishmaniasis	00	00	06 HB=6	00	00	03 KN=3	05 AP=4 PO=1	01 MO=1	00	15	11	748	524	- 42.7 %

Key to Table 1 & 2

Provinces: **W**: Western, **C**: Central, **S**: Southern, **N**: North, **E**: East, **NC**: North Central, **NW**: North Western, **U**: Uva, **Sab**: Sabaragamuwa.

DPDHS Divisions: **CB**: Colombo, **GM**: Gampaha, **KL**: Kalutara, **KD**: Kandy, **ML**: Matale, **NE**: Nuwara Eliya, **GL**: Galle, **HB**: Hambantota, **MT**: Matara, **JF**: Jaffna, **KN**: Killinochchi, **MN**: Mannar, **VA**: Vavuniya, **MU**: Mullaitivu, **BT**: Batticaloa, **AM**: Ampara, **TR**: Trincomalee, **KM**: Kalmunai, **KR**: Kurunegala, **PU**: Puttalam, **AP**: Anuradhapura, **PO**: Polonnaruwa, **BD**: Badulla, **MO**: Moneragala, **RP**: Ratnapura, **KG**: Kegalle.

Data Sources:

Weekly Return of Communicable Diseases: Diphtheria, Measles, Tetanus, Whooping Cough, Chickenpox, Meningitis, Mumps.

Special Surveillance: Acute Flaccid Paralysis.

Leishmaniasis is notifiable only after the General Circular No: 02/102/2008 issued on 23 September 2008.

Dengue Prevention and Control Health Messages

Check the roof gutters regularly for water collection where dengue mosquitoes could breed.

Table 4: Selected notifiable diseases reported by Medical Officers of Health

01st – 07th September 2012 (36thWeek)

DPDHS Division	Dengue Fever / DHF*		Dysentery		Encephalitis		Enteric Fever		Food Poisoning		Leptospirosis		Typhus Fever		Viral Hepatitis		Human Rabies		Returns Received
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	%
Colombo	91	6938	2	99	0	8	2	145	0	31	7	133	0	3	2	84	0	3	**77**
Gampaha	110	5790	1	70	0	12	3	48	1	25	5	176	0	16	6	243	0	0	**100**
Kalutara	30	2037	1	77	0	2	1	37	0	26	3	180	0	3	0	28	0	2	**69**
Kandy	31	1828	2	83	0	2	0	17	0	56	2	54	4	95	4	58	0	0	**87**
Matale	19	401	2	71	0	5	1	9	0	7	0	33	0	3	0	32	0	0	**92**
Nuwara	7	266	1	148	0	3	1	23	0	8	1	31	0	55	1	17	0	1	**77**
Galle	24	1201	5	100	0	6	1	11	0	17	4	96	4	59	0	2	0	0	**84**
Hambantota	6	431	1	27	0	2	0	6	1	28	1	63	3	40	0	18	0	0	**92**
Matara	24	1219	1	56	0	8	1	16	0	19	5	113	1	65	0	98	0	0	**100**
Jaffna	10	330	2	136	0	13	5	296	1	71	0	2	0	250	2	15	1	1	**100**
Kilinochchi	0	67	0	10	0	2	0	28	0	40	0	4	0	29	0	4	0	1	**25**
Mannar	0	123	0	51	0	4	0	21	0	16	0	20	0	42	0	2	0	0	**60**
Vavuniya	9	60	2	24	0	21	0	8	0	15	0	18	1	3	0	1	0	0	**100**
Mullaitivu	0	20	0	16	0	1	1	8	0	2	0	3	0	5	0	0	0	0	**25**
Batticaloa	1	602	6	158	0	2	0	15	0	306	0	8	0	0	0	6	0	4	**57**
Ampara	0	107	0	65	0	2	0	5	0	9	0	23	0	0	0	2	0	0	**57**
Trincomalee	0	123	7	135	0	2	0	16	0	11	0	37	0	17	0	4	0	0	**33**
Kurunegala	57	1712	2	142	0	14	0	75	1	34	1	116	2	25	7	115	0	4	**81**
Puttalam	79	944	2	59	0	6	0	11	0	10	0	31	1	14	1	5	0	2	**67**
Anuradhapu	4	276	1	64	0	6	0	12	0	18	0	74	0	21	0	55	0	1	**47**
Polonnaruw	2	190	3	42	1	2	0	2	0	1	0	45	1	3	0	37	0	1	**71**
Badulla	8	258	6	94	0	3	2	47	0	3	2	33	6	89	0	36	0	0	**88**
Monaragala	4	202	0	48	0	4	0	18	0	7	0	57	2	66	1	149	0	2	**82**
Ratnapura	66	3051	5	165	0	25	0	42	0	12	3	236	1	36	2	86	0	1	**61**
Kegalle	56	2089	2	48	0	9	0	20	0	10	3	133	1	49	8	447	0	0	**91**
Kalmune	0	172	4	203	0	1	0	5	3	80	1	3	0	0	0	7	0	3	**46**
SRI LANKA	**638**	**30473**	**58**	**2191**	**01**	**165**	**18**	**941**	**07**	**862**	**38**	**1722**	**27**	**988**	**34**	**1551**	**01**	**26**	**75**

Source: Weekly Returns of Communicable Diseases WRCD).
***Dengue Fever / DHF** refers to Dengue Fever / Dengue Haemorrhagic Fever.
****Timely** refers to returns received on or before 27thAugust, 2012 Total number of reporting units 329. Number of reporting units data provided for the current week: 209
A = Cases reported during the current week. **B** = Cumulative cases for the year.

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Comments and contributions for publication in the WER Sri Lanka are welcome. However, the editor reserves the right to accept or reject items for publication. All correspondence should be mailed to The Editor, WER Sri Lanka, Epidemiological Unit, P.O. Box 1567, Colombo or sent by E-mail to **chepid@sltnet.lk.**

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