Utilization of National Health Insurance Database to Analyze Medication Risk in Taiwan

~ Aspects of IPR and Drug Pricing Policy ~

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Background and Objective of the Study

1. Irrational medication is part of the culture.
2. Campaign for pharmacovigilance planning (PvP) is like canoeing upstream.
3. Risk from drug overuse starts to call for public attention.
4. PE study is important for identifying risk (ICH E2E).
5. National Health Insurance Research Database-Taiwan (NHIRD) is powerful for PE studies.
6. Malpractice of pharmaceutical IPR might be a key factor causing irrational medication.
7. The impact of IPR and drug pricing policy on drug consumption and expenditure was investigated.

Education on Safe Medication for the silver-hair

1. *>500 pharmacists/year were involved as lecturers.*
2. *>100 pharmacy students served as teaching assistants.*

via 50 community colleges

"Drug Free Teenagers" Program

>200 pharmacy college kids meet pre-teenagers.

via 370 elementary schools

I am the gatekeeper of my grandparents' medication.

Risk of Irrational Medication

Table 1. Profile of Unbalanced distribution of pharmacy service

	Taiwan	OECD
physician's visits (times/person/year)	15.2	5.9
Drug items per prescription	4.2	1.9
Drug expenditure to total NHI cost	25%	~15%
No. of daily dispensing by hospital pharmacist	151	37
No. of daily dispensing by community pharmacist	33	
% of patients with chronic disease	18%	--
% of refills released to community pharmacy	2%	100
community pharmacy contract with NHI	52%	--

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Undetermined Risk: Risk Factor goes to Individual or System?

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ORIGINAL REPORT

Usage of the claim database of national health insurance programme for analysis of cisapride-erythromycin co-medication in Taiwan†

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SUMMARY

Purpose: This study aimed to use the National Health Insurance Research Database, Taiwan for risk analysis of concomitant use of cisapride and erythromycin.

Methods: The sample consisted of subjects identified in the Outpatient Sampling Database (OSD) and Longitudinal Health Insurance Database 2000 (LHID 2000), derived from the original claim data of the National Health Insurance Research Database, Taiwan.

Results: According to the LHID 2000, a total of 464 individuals experienced 685 episodes of cisapride-erythromycin co-medication prescribed by 295 physicians, revealing a prevalence of 4.5% concomitant use, with higher prevalence in clinics (9.2%) than in other medical institutes (3.7–5.4%). Among the co-medication episodes, 81.9% and 61.2% were prescribed from the same health institutes and by the same physicians, respectively. No medical record of cardiac arrhythmias was found among these patients in 2001 and 2002, probably due to the fact that 78.9% of the 464 individuals were under age 16, 84.0% had short exposure duration (1–4 days) and 98.6% of the episodes were prescribed with a cisapride dose of less than 0.8 mg/kg/day.

Conclusions: Findings from this study suggest that there exists an urgent need for accreditation in terms of pharmacovigilance of clinical sites and their practicing physicians for the prevention of irrational concomitant prescription in Taiwan. Our findings also indicate that it is necessary to investigate other possible conditions of potentially dangerous co-medication in Taiwan and other developing countries.

Risk from drug overuse calls for public attention.

Table 2. Incidence of ESDR in Taiwan.

year	ESRD	prevalence
1997	20,697	1/1051
1998	23,758	1/923
1999	26,920	1/821
2000	29,937	1/744
2001	33,317	1/672
2002	35,965	1/626
2003	39,574	1/571
2004	42,550	1/533
2005	45,718	1/498

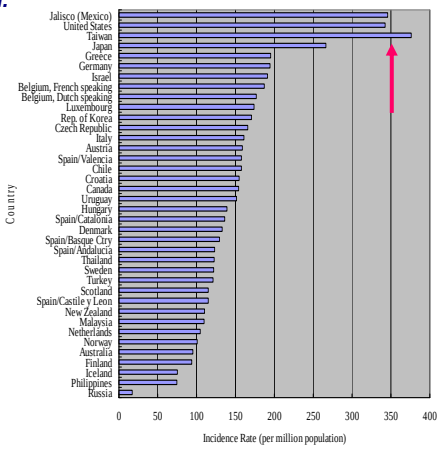

Fig 1. Comparison of Prevalence of ESRD.

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From GPP to GPDP

Risk exists where pharmacists' effort can not reach.

Good Pharmacy & Delivery Practice

Pharmacists

medicine

Patient, product and information dissemination

NHI Policy– IPR & pricing

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NHI Pricing Policy not Based on Drug IPR

Definition and Pricing of NHI payable Medicine

1. *Patented proprietary medicine (PM)*
2. *Off-patent proprietary medicine (OPM)*
3. *BE generic medicine (BEGM): 80% or less to OPM*
4. *Generic medicine (GM): 80% or less to OPM*

* *Hatch-Waxman Act-USA: drug pricing & patent restoration act*
* *BE is required for generic approval since 1988 in Taiwan.*

Consequences:

1. *Everlasting better pay on OPM ended with unfair competition and complicated pharmacoeconomic profile in medical circle.*
2. *Granted protection to OPM led to unnecessary NHI expenditure.*
3. *Patient risk due to drug overuse is under-estimated.*

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Pricing Policy Stimulates Clinical Trials

OPM gets everlasting better pay.

⇒ *Desire to be the first runner stimulates CT .*

⇒ *Is quality being sacrificed?*

⇒ *risk might be underestimated.*

⇒ *Ethical and human right issue.*

⇒

www.habsgirls.org.uk/ images

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Method for Risk Analysis Studies

- Database of National Health Insurance for Research (NHIRD):
  1. Systematic Sampling Database (SSD)
  2. Longitudinal Health Insurance Database (LHID)
  3. Speicial Disease Sampling Database (SDSD)
  4. All sampling databases have ambulatory and inpatient subsets
- Data retrieved: NHI payable price and amount used of year 2002 to 2004
- References
  1. Global statistics of NHI -Taiwan, http://www.nhi.gov.tw
  2. Pricing http://www.nhi.gov.tw/inquire/query1.asp?menu=1 & menu id=8
  3. Expenditure http://www.nhi.gov.tw/webdata/webdata.asp?menu=3
  4. OECD reform of health care systems ─A review of 17 OECD countries.
  5. Merck Index
  6. Taiwanese Physicians' Desk Reference, CA Chen ed., 2006, Taiwan
  7. Physicians' Desk Reference. Medical Economics Company, Montvale, NJ.

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IPR status of the top 200 NHI payable drugs

Table 3: Number of drugs classified by IPR and unit price status.

Years off patent	No. of medicine	unit price			Information unclear
		OPM>GM	OPM<GM	OPM=GM	
0	19	5	0	0	14
1-5	34	19	1	0	14
6-10	30	20	1	1	8
11-15	16	11	1	0	4
16-20	30	14	5	2	9
21-25	22	11	3	0	8
26-30	9	4	0	1	4
>30	3	3	0	0	0
Unclear	37	7	1	3	26
Total	200	94	12	7	87

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Price gap of OPMs and GMs ranged between 1.28 to 3.76.

Table 4: Statistics of the highest 10 reimbursed drug items in year 2004.

	Rank	Active ingredient	Years off patent	Market share of OPM %	Price of OPM NTD (O)	Highest GM price NTD (G)	Price gap (O/G)
1	1	Amlodipine 5mg Tab	3	100	19	14.4	1.32
2	15	Ciprofloxacin 2mg/ml Inj (100ml)	3	N/A	1045	499	2.09
3	30	Diclofenac 25mg SC. Tab	20	66	4.14	1.1	3.76
4	86	Pentoxifylline 100mg SC. Tab	20	28	3.44	2.43	1.42
5	98	budesonide 200 mcg Inh (40mg)	13	0.5	846	630	1.34
6	128	Ipratropium 0.25 mg/ml Inh (2ml)	18	89	25.4	19.8	1.28
7	146	Diphenidol 25mg Tab	40	56	2.71	1	2.72
8	178	Metoclopramide 3.84 mg FC Tab	24	75	1.08	0.6	1.8
9	186	Cyproterone 50mg Tab	21	100.	59	39.6	1.49
10	199	Acebutolol 400mg Tab	17	93	14.4	10.9	1.32

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NHI could have saved 1.05 billion NTD in year 2002 on the top 10 OPMs if they were paid with the highest GM price.

Table 5: The top 10 NHI payable drugs in year 2002.

Rank	Active ingredient	Years off patent	Market share of OPM (%)	unit price reimbursed from NHI			NHI Extra payment million NTD (P-G)*Qa
				OPM (P)	Highest GM price (G)	Price gap (P/G)	
1	Amilodipine, 5mg tab.	1	100	19	14.4	1.32	510
2	Cefazolin, 1 gm vial	15	15	94	77	1.22	30
3	Nifedipine, 30 mg oros	16	40	18.4	16.5	1.12	43
4	Gliclazide, 80mg sr tab	16	---	8.5	--	---	---
5	Metformin, 500 mg fc tab	19	28	2.84	2.7	1.05	13
6	Valsartan, 80 mg caps	NA	100	27.1	--	---	---
7	Felodipine, 5 mg tab	4	64	17.5	16	1.09	48
8	Losartan, 50 mg fc tab	NA	100	27.6	22	1.25	171
9	Enalapril, 20 mg tab	4	33	20.5	15.9	1.29	61
10	Diclofenac, 25 mg sc tab	18	19	6.5	1.43	4.55	179
	Sum of Extra payment of Item 1-10						1,059

NA: Not expired in 2002, Qa: quantity of drug consumption.

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NHI could have saved 772 million NTD on OPM in year 2004 for the top 10 drugs with largest price gap.

Table 6. The top 10 drug items with largest price gap between OPM and GM in year 2002.

Rank	Active ingredient	Years off patent	Market share of OPM (%)	unit price reimbursed from NHI			Extra payment (P-G)×Qa million NTD
				OPM (P)	Highest GM price (G)	Price gap (P/G)	
1	Amlodipine	3	100	19	14.4	1.32	632
15	Ciprofloxacin	3	87	1045	499	2.09	24
30	Diclofenac 25mg	20	19	4.14	1.1	3.76	5
86	Pentoxifylline	20	49	3.44	2.43	1.42	7
98	Budesonide 200	13	69	846	630	1.34	26
128	Ipratropium 0.25	18	89	25.4	19.8	1.29	32
146	Diphenidol 25mg	40	7.50	2.72	1	2.72	1
178	Metoclopramide	24	92	1.08	0.6	1.80	25
186	Cyproterone	21	100	59	39.6	1.50	2
199	Acebutolol	17	68	14.4	10.9	1.32	18
						Sum of Extra payment for Items 1-10	772

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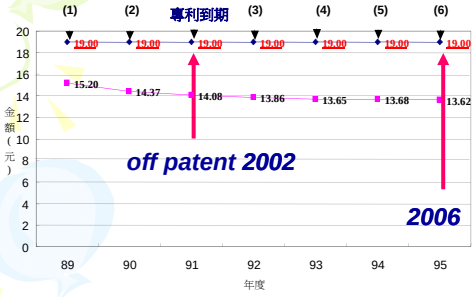
Impact of Price Protection on OPM Amilodipine



1. Amilodipine consumption ↑24% from 2003 to 2005.
2. No GMs were launched until 2006.
3. NHI extra payment implied drug overuse.

Table 7. Impact of drug pricing policy on amilodipine consumption

year	Year off patent	OPM Price (P)	Highest GM price (G)	Price gap (P/G)	Market share of OPM (%)	Relative OPM consumption	NHI Extra payment on OPM (mNTD)*
2003	1	19.0	14.4	1.32	100	1.0	511
2005	3	19.0	14.4	1.32	100	1.24	632

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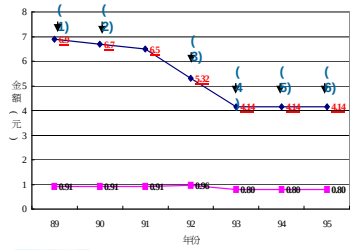
* (Pa-Pb) xquantity

Impact of Price Protection on OPM Diclofenac



Change of price gap: 4.14 to 3.76

Change of market share: 19% to 9%

Change of consumption: 1 to 0.49

Off-patent at 1966

Table 8. Impact of drug pricing on diclofenac consumption

year	Year off patent	OPM Price (P)	Highest GM price (G)	Price gap (P/G)	Market share of OPM (%)	Relative OPM consumption	NHI Extra payment on OPM (mNTD)*
2003	38	6.5	1.43	4.14	19	1.0	179
2005	40	4.1	1.1	3.76	9	0.49	5

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** (Pa-Pb) xquantity*

CONCLUSION

The report led to authority's position statement: Generic substitution

2006-05-11-China Times

2007-08-13-Med News


藥價後續調整引發土洋藥廠先後抗議

健保局：反映市場真實狀況如期調降

已兼顧資源合理分配與民眾用藥權益

System building for Safe Medication
~ The voice from Taiwanese Pharmacists ~

THANK YOU

Conclusion

1. ***System Building for risk minimization is important in societies like Taiwan where irrational medication is prevalent.***
2. ***PE studies for risk analysis led important input to public policy.***
3. ***PvP challenged the culture, the medical profession, the pharmaceutical industry and the political environment.***

3. Consumers have responsibility for implementing PvP.

Consumer protection
Low risk society
Fairness of trade → ***System***, ***Professionals***, ***Consumers***
Concerned citizens