The Effect of Introducing Inpatient Mandatory Generic Drug Substitution at Ramathobodi Hospital

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Background: *Generic substitution is a mechanism for reducing drug expenditure in many healthcare settings. Ramathibodi, a teaching hospital, has introduced mandatory generic drug substitution (228 items) for health schemes in inpatient service since September 1, 2009.*
Objective: *Explore prescribing patterns in overall and by patients' health schemes between Thai fiscal year 2009 and 2010, and estimate possible saving if this policy was extended to the outpatient service.*
Material and Method: *Prescribing data and registered populations between October 1, 2008 and September 30, 2010 were retrieved from the database and analyzed.*
Result: *Original and generic expenditure rose 8.42 and 8.61% from 2009 to 2010 respectively. Among 228 mandatory items, more original was switched to generic drugs, both in terms of value (6.5 to 7.2%) and in terms of volume (32.5 to 33.8%). Some inpatients, mainly civil servants and self-pay patients, requested the original from the outpatient service where the mandatory substitution was not applied. If the policy were extended through all services, the government would save approximately 306.5 million Baht (US$ 10.1 million) per year. However, the hospital would reduce its profit by 53.1 million Baht (US$ 1.7 million).*
Conclusion: *After the policy was launched, more original mandatory drugs were switched to generic. To gain more saving, the policy may be expanded to outpatient service, and/or mandatory drug list should be reviewed periodically.*

Keywords: *Generic substitution, Drug expenditure, Hospital database, Thai teaching hospital*

J Med Assoc Thai 2012; 95 (4): 519-25
Full text. e-Journal: *http://www.jmat.mat.or.th*

Thai health expenditure has rapidly increased over the past few years. International Health Policy Program revealed that, between 2005 and 2008, total health expenditure has risen from 251,693 million Baht or US$ 8,279 million (30.4 Baht: 1 US$) to 367,767 million Baht or US$12,098 million at current year prices[1]. These accounted for 3.5% and 4.0% of national GDP. A large portion of such costs was drug expenditure. In 2005, approximately 43% of total health expenditure was from drug items, of which 56.3% was imported and 43.7% was locally made[2].

To control this escalating cost, drug utilization management strategies were widely promoted in health care settings. One of them was the use of generic or generic substitution, either optional or mandatory. Generic substitution refers to the policy of a health plan to pay for a generic drug. The policy will pay for a generic, unless no generic equivalent is available[3]. In Thailand, Tantivess S et al surveyed the use of generic in public and private hospitals and determined their savings after the economic crisis in 2000[4,5]. Other studies evaluated possible prescription cost savings through government hospital formularies in 2010[6]. In addition to the economic outcome, in 2008, Plianbangchang P et al explored physicians' prescribing behavior in outpatient departments of district hospitals in Phitsanulok, Thailand[7]. Ramathibodi Hospital, a Thai teaching hospital in Bangkok, introduced inpatient mandatory generic drug substitution for 228 items since September 1, 2009. These items were approved by the hospital's Pharmaceutical and Therapeutic Committee (PTC) as having the same bioequivalent and therapeutically equivalent to its original counterpart. Only generic

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drugs are dispensed to patients in case of admission. However, original drugs are still available in outpatient cases because the hospital can be reimbursed. Some admitted patients use this way to request original drugs as home medicine or buy drugs prior to be admitted. The present study was conducted to explore prescribing patterns of mandatory generic substitution in inpatient service by patient's health scheme and assess the extent saving to which mandatory generic substitution is also practiced in the outpatient service. The information obtained will be useful as a feedback to improve drug utilization management strategies to control drug expenditure in the hospital.

Material and Method

Prescribing data and registered populations between October 1, 2008 and September 30, 2010 (Thai fiscal year, FY 2009 to 2010) were retrieved from the hospital database in the format of Microsoft Visual Fox Pro 9.0. Retrieved data was imported to Microsoft Access 2007 and analyzed by Microsoft Access 2007 and Excel 2007.

Retrieved data was comprised of prescribed date, patient's hospital number (HN) and health insurance schemes (universal coverage (UC), social security scheme (SSS), civil servants medical benefit scheme (CSMBS), or self-pay) of each visit/admission, prescribing date, drug's code, quantity of drug dispensed, and unit selling price.

Physician's prescribing pattern was measured by value and volume of drug sold. Value of drug sold was calculated by (unit selling price) x (quantity of drug dispensed) and volume of drug sold was directly from quantity of drug dispensed. Value and volume of drug sold for both in and outpatients were then calculated and compared between fiscal years.

Each drug was classified to be original if it was developed and sold by an original pharmaceutical company, while generic drug was one that was made other than by the original developer with bioequivalent and therapeutically equivalent to its original counterpart. By classified drugs under hospital's inpatient mandatory generic lists as "substitution", drugs other than 228 substituted pairs were identified as "no substitution". Among 228 items (Table 1), drugs were also identified as "already substituted" when generics were dispensed as mandated, and as "able to be substituted" when originals were still dispensed even they should be switched (such as home medicines).

To find whole hospital's substitution rate, proportions of drug value and volume were calculated by drug substitutability as 1) able to be substituted, 2) already substituted, and 3) no substitution. Furthermore, drugs able to be substituted in 2010 were analyzed and investigated for any reason they were not switched to generics by health scheme, in terms of value and volume, respectively.

Finally, budget impact analysis was performed as if all mandatory drug substitution was strictly applied to all 228 drugs, both in and outpatients. Substitutable drugs in 2010 were filtered and analyzed in two scenarios. In scenario 1 or base case, data of substitutable original drugs both in and outpatients were retrieved. Value of drug sold was calculated as (quantity of original drugs able to be substituted) x (unit selling price). Value of drug cost was (quantity of original drugs able to be substituted) x (unit buying cost). In scenario 2 or applying mandatory generic drug, data of prescribed drugs in scenario 1 were substituted to their mandatory generic match by generic name, dosage form, and strength. Its value of drug sold was calculated as (quantity of generic substituted drugs) x (unit selling price), value of drug cost as (quantity generic substituted drugs) x (unit buying cost). Profits for both scenarios were calculated as value of drug sold – value of drug cost and then compared.

Results

A comparison of the total value and volume of drug sold in fiscal year 2009 and 2010 was performed

Table 1. Inpatient mandatory generic drug substitution by MIMS classification at Ramathibodi Hospital

MIMS classification	Number of substituted items
Cardiovascular & hematopoietic system	47
Central nervous system	33
Anti-infectives (systemic)	29
Oncology	21
Gastrointestinal & hepatobiliary system	17
Dermatologicals	14
Respiratory system	11
Endocrine & metabolic system	11
Musculo-skeletal system	10
Eye	10
Allergy & immune system	7
Others	18
Total	228

by drug sources, defined as original or generic (Table 2). By value, most of drug sold was original, accounted for 87.8% in both fiscal years. However, from 2009 to 2010, original drug value increased from 3.55 to 3.85 billion Baht or 8.42%, while generic increased from 0.49 to 0.54 billion Baht or 8.61%. By volume, in contrast, only one-third of drug issued was original in both years (35.4 and 36.2%, respectively). There was no change for original and -0.03% change for generic drugs.

In terms of substitutability, 79.2 and 80.2% of total hospital's drug value had no mandatory substitution in 2009 and 2010, respectively (Fig. 1). About 20% of each year total drug value had substitutable drugs (228 pairs). Among these, 6.5 and 7.2% had been substituted and 14.2 and 12.6% had not yet been switched. By volume, 60.2 and 59.3% had no mandatory drug substitution in 2009 and 2010 (Fig. 2), 32.5 and 33.8% had been substituted while 7.3 and 6.9% had not.

To figure out the reasons why not all 228 mandatory original drugs have been substituted by their generics, substitutable drugs in 2010 were selected and analyzed. Table 3 and 4 showed the proportion of drug under the list by service type and patient's health scheme. For inpatient service, where any of mandatory original drugs will be switched to generic automatically when found; by drug volume, 97.2, 97.7, 95.8, and 96.1% was properly switched for patients under universal coverage (UC), social security scheme (SSS), civil servants medical benefit scheme (CSMBS), and self-pay, respectively. However, by drug value, 90.3 and 90.9 percent was substituted to generics for patients under UC and SSS, while 51.3 and 72.2% was applied for patients under CSMBS and self-pay. Most of unable to switch original to generic in CSMBS and self-pay (44.0 and 21.6%) was drugs bought from outpatient service where the system allowed original drugs. Other minor reason was from home medication (4.7 and 6.2%). For outpatient service, since the system was still able to dispense

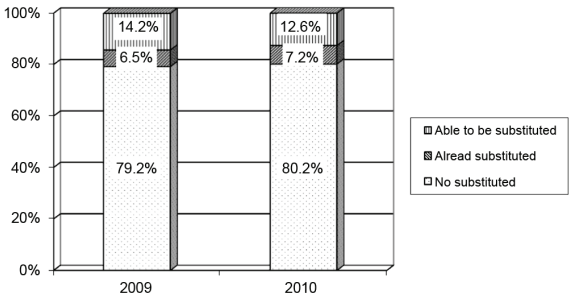

Fig. 1 Proportion of drug value both in and outpatients by type of substitution, FY2009 vs. 2010

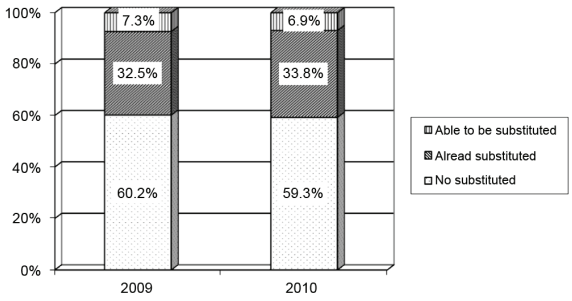

Fig. 2 Proportion of drug volume both in and outpatients by type of substitution, FY2009 vs. 2010

mandatory drugs, by volume, 4.5, 3.8, 26.4, and 17.5% of mandatory drug was original for patients under UC, SSS, CSMBS, and self-pay, respectively. By drug value, 11.3 and 12.5% was dispensed as original for patients under UC and SSS, while higher rate at 78.3 and 64.5% was applied for CSMBS and self-pay patients.

Table 5 estimates the financial impact to the hospital if all mandatory original drugs were substituted by generics. In base case, value of substitutable original drugs was 555.3 million Baht at selling price and 444.9 million Baht at cost. Therefore, the hospital got a benefit from this difference at 110.4 million Baht. In scenario 2, all substitutable original

Table 2. Value and volume of drug sold both in and outpatients in FY 2009 and 2010

	2009	2010	% change in 2010
Value of drug sold (% to total)			
Original drug	3,549,892,336 (87.8%)	3,848,992,562 (87.8%)	8.42%
Generic drug	494,252,135 (12.2%)	536,812,924 (12.2%)	8.61%
Volume of drug dispensed (% to total)			
Original drug	88,076,664 (35.4%)	88,048,996 (36.2%)	0.00%
Generic drug	160,895,405 (64.6%)	155,252,024 (63.8%)	-0.03%

Table 3. Proportion of drug value under 228 mandatory generic substituted drugs by health scheme in FY2010

	UC	SSS	CSMBS	Self-pay
Inpatient				
Already substituted	90.3%	90.9%	51.3%	72.2%
Able to be substituted				
Buy from outpatient	7.0%	5.9%	44.0%	21.6%
Others (*e.g.* home medicine)	2.7%	3.2%	4.7%	6.2%
Outpatient				
Already substituted	88.7%	87.5%	21.7%	35.5%
Able to be substituted	11.3%	12.5%	78.3%	64.5%

UC = universal coverage; SSS = social security scheme; CSMBS = civil servants medical benefit scheme

Table 4. Proportion of drug volume under 228 mandatory generic substituted drugs by health scheme in FY2010

	UC	SSS	CSMBS	Self-pay
Inpatient				
Already substituted	97.2%	97.7%	95.8%	96.1%
Able to be substituted				
Buy from outpatient	0.3%	0.1%	0.8%	0.2%
Others (*e.g.* home medicine)	2.5%	2.2%	3.4%	3.7%
Outpatient				
Already substituted	95.5%	96.2%	73.6%	82.5%
Able to be substituted	4.5%	3.8%	26.4%	17.5%

UC = universal coverage; SSS = social security scheme; CSMBS = civil servants medical benefit scheme

Table 5. Budget impact analysis (in Thai Baht) in case of applying mandatory generic drug substitution to both in and outpatients in FY2010

Scenario	Value of drug sold	Value of drug cost	Profit
1: Base case	555,352,689	444,901,890	110,450,799
2: Applying mandatory generic drug substitution to both in and outpatients	248,862,952	191,518,146	57,344,806
Difference	306,489,737	253,383,744	53,105,993

drugs in base case was switched to generic and calculated for profit by using generics' selling prices and buying costs. In this scenario, value of drug sold and drug cost were 248.9 and 191.5 million Baht. As a result, the benefit to the hospital was less than base case at 57.3 million Baht.

Discussion

The finding shows that after the introduction of 228 items inpatient mandatory generic drug substitution on September 1, 2009, proportion of mandatory generic use was increased from 32.5% in 2009 to 33.8% in 2010 by volume of drug dispensed (Fig. 2) and from 6.5% to 7.2% by value of drug sold (Fig. 1). However, percent of overall generic dispensed was decreased from 64.6% to 63.8% (Table 2) while its value was constant at 12.2%. One possible reason was a patient switched drug from substitutable to other original drug for the identical therapeutic effect that was not in mandatory list. Another reason was that some inpatients, especially under CSMBS, requested their drugs from the outpatient service where the mandatory generic substitution was not applied. Although, by volume, 95.8% of substitutable drug

dispensed to CSMBS inpatients had already switched to generic (Table 4); by value, contributed to small sales of more expensive original, generic's value was only 51.3% (Table 3). This is in line with a study of Tantivess S. in 2000, reporting that patients under CSMBS trended to have original than generic drugs[5]. Her study surveyed selecting criteria of drugs that had both original and generic available in 73 hospitals in Thailand. Fifty-two percent of prescribed drugs were considered by type of patient's health scheme or their ability to pay. Others were by patient's request or non-response to generic or drug's adverse reaction. Among these, original was reported to be able to dispense to patients under CSMBS in every hospital, while 40.7% was able for SSS and 25.9% for UC. The study also revealed how to promote more generic use. Mainly was to ensure user generic drugs' efficacy and safety. The top three suggestions from hospital's pharmacist perspective were improving bioequivalent quality standard (54.4%), monitoring generic drug in the market periodically (51.2%), and reporting bioequivalent laboratory result (40.8%). Another study by Plianbangchang P et al in 2008 explored physicians' prescribing behavior in outpatient departments of district hospitals in Phitsanulok, Thailand[7] and found that drug prescribed by brand names varied in their therapeutic class. About 28.8% of prescriptions written by brand name were fixed dose combination drugs. Although all brand name prescriptions were off patented, physicians often recalled when writing their prescription. One possible reason was once a physician learned drug's brand name; it may be difficult to change when other generics arrived. The author encouraged Thai Food and Drug Administration (FDA) to develop generic registration policy, instead of current brand name registration.

Generic substitution was also widely promoted in many countries to control escalating drug expenditure. In Sweden, mandatory generic substitution was introduced in 2002[8]. National sales data, between January 2000 and June 2005, was analyzed and found that, in most therapeutic groups, there has been an increase in the volumes of substitutable pharmaceutical, ranging from one third to three times the initial volumes whereas the volumes of non-substitutable pharmaceuticals have declined. In 2004, Morgan SG et al revealed cost drivers in the pharmaceutical sector of British Columbia senior's prescription[9]. Between 1991 and 2001, expenditures on prescription drugs increased from $149 to 320 million. The increase was contributed to increases in the population of seniors and the rate at which they utilized therapies ($91 million), changes in the mix of therapies and the type of product selected ($111 million), drugs' price ($5 million). While increased generic substitution significantly reduced the price of products selected over the period ($-36 million).

The authors' budget impact analysis showed that in case of expanding mandatory generic drug substitution to outpatients by using the number of drug sale in FY 2010, the hospital would have 53.1 million Baht or US$ 1.7 million profit lost. However, in government perspective, possible saving would be approximately 306.5 million Baht or US$ 10.1 million per year. In 2002, Tantivess S, et al surveyed 166 hospitals in Thailand to estimate saving from 10 new generic drugs registered to Thai FDA[4]. In the first two years after generics were launched (1999-2000), with the voluntary substitution, total saving from 166 hospitals was 216.6 million Baht or US$ 7.1 million. In addition, if mandatory substitution were applied, the possible saving would be increased to 251.9 million Baht or US$ 8.3 million. The author discussed that not only drug expenditures had decreased, patients could also have more opportunity to get drug since its price was lower. Possible savings from generic substitution were reported in many studies worldwide. In Australia, a commentary from a community pharmacy perspective was provided that currently generic drugs accounted for only 15% of the total Pharmaceutical Benefits Scheme (PBS) budget, which are lower than in most comparable countries[10]. The study suggested that, in timely and efficient manner of Australian residents, the government should use this opportunity to promote generic use to achieve savings in the overall cost of the PBS and that will allow consumers access to medications at the lowest price and will provide space for PBS listing of new and expensive drugs. In South Africa, generic prescribing by private medical practitioners and generic substitution by private pharmacists had been practiced since 1984[11]. Karim AS, et al studied possible saving from these policies in 1992 by collecting prescriptions from 10 pharmacists on four randomly selected days. One thousand five hundred seventy prescriptions with 4,086 items were reviewed and found that about 6.8% of the cost of the original prescriptions could be saved if total generic substitution was practiced. Another study by Fischer MA and Avorn J was performed in 2000[12]. Data on Medicaid drug spending for 48 states and the District of Columbia was analyzed and identified potential savings of US$229 million from greater use of generic

drugs. Furthermore, if the best available prices from each state had been used nationally, savings would have increased to US$450 million.

In the present study, generic was assumed to have the same efficacy and safety as the original. A sizable saving was then resulted. The present study also estimated only the effect of direct medicine cost in hospital's perspective. For further study, other direct cost, indirect cost, and clinical outcomes should also be taken into account.

Conclusion

Generic substitution was one of drug utilization management strategies to control high drug expenditure in health care settings. The paper found that although generic drug substitution was launched mandatory to inpatient service and more substitutable original was switched to generic, patients, especially under CSMBS and self-pay, were still able to request original drugs from outpatient service. The present study provided a feedback to hospital administrators to control the utilization more effectively. To increase saving, mandatory substitution should be applied in outpatient service as well. In addition, substitutable drugs list should be reviewed periodically.

Potential conflicts of interest

None.

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ผลจากการบังคับใช้ยาสามัญทดแทนยาต้นแบบในงานผู้ป่วยในของโรงพยาบาลรามาธิบดี

สมิง เก่าเจริญ, อรลักษณ์ พัฒนาประทีป

การใช้ยาสามัญทดแทนยาต้นแบบเป็นกลไกหนึ่งในการควบคุมค่าใช้จ่ายยาที่สูงขึ้นในหลายองค์กร โรงพยาบาลรามาธิบดี หนึ่งในโรงพยาบาลโรงเรียนแพทย์ในประเทศไทยได้บังคับใช้มาตรการยาสามัญทดแทนยาต้นแบบ ในงานผู้ป่วยในทุกสิทธิการรักษารวม 228 ชนิด ตั้งแต่วันที่ 1 กันยายน พ.ศ. 2552 การศึกษานี้มีวัตถุประสงค์เพื่ออธิบายรูปแบบการสั่งจ่ายยาโดยรวม และตามสิทธิการรักษาของผู้ป่วยใน ปีงบประมาณ พ.ศ. 2552 ถึง พ.ศ. 2553 และเพื่อประมาณผลกระทบในกรณีที่มีการขยายมาตรการไปยังงานผู้ป่วยนอก ข้อมูลการสั่งจ่ายยาและการลงทะเบียนของผู้ป่วยระหว่างวันที่ 1 ตุลาคม พ.ศ. 2551 ถึง 30 กันยายน พ.ศ. 2553 ถูกนำมาวิเคราะห์ พบว่าโดยรวมค่าใช้จ่ายยาต้นตำรับและยาสามัญเพิ่มขึ้นร้อยละ 8.42 และ 8.61 ตามลำดับ ในส่วนของยา 228 ชนิด พบว่ามีการใช้ยาสามัญมากขึ้นจากร้อยละ 6.5 เป็น 7.2 ในด้านมูลค่ายา และจากร้อยละ 32.5 เป็น 33.8 ในด้านปริมาณการใช้ อย่างไรก็ตามผู้ป่วยส่วนหนึ่งโดยเฉพาะสิทธิข้าราชการและจ่ายเงินสด ได้ขอเบิกยาจากงานผู้ป่วยนอก ซึ่งยังไม่มีการบังคับใช้มาตรการบังคับใช้ยาสามัญทดแทนยาต้นแบบ กรณีมีการขยายมาตรการนี้ไปงานผู้ป่วยนอกจะส่งผลให้โรงพยาบาลได้รับกำไรลดลง 53.1 ล้านบาท อย่างไรก็ตามในมุมมองของรัฐบาลจะสามารถประหยัดค่าใช้จ่ายยาได้ประมาณ 306.5 ล้านบาทต่อปี โดยสรุป ภายหลังการบังคับใช้มาตรการยาสามัญทดแทนยาต้นแบบ พบว่าการใช้ยาสามัญทดแทนยาต้นตำรับมีมากขึ้น แต่เพื่อให้มีการประหยัดค่าใช้จ่ายที่มากขึ้น โรงพยาบาลอาจทำการขยายมาตรการไปยังงานผู้ป่วยนอก และ/หรือ เพิ่มรายการยาที่มีการบังคับให้ใช้ยาสามัญทดแทนมากขึ้น