Generic Substitutions: A 2005 Survey of the Acceptance and Perceptions of Physicians in Jamaica

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ABSTRACT

In Jamaica, the 1993 amendment to the Pharmacy Act allows pharmacists to offer patients generic substitutions for innovator brands; however, there were reservations among physicians about this policy implementation. The success of the amendment may be influenced by the confidence of physicians in the therapeutic equivalence of generics, especially since the act also allows physicians to indicate "no substitution" on prescriptions. The aim of this investigation was to examine the current attitudes of physicians towards the use of generic substitutions. One hundred questionnaires were distributed island-wide among physicians of varying specialities, with items to characterize their demographics and specific statements to determine their perception of generics. Sixty questionnaires were returned completed (60% response). Most of the responding physicians were males (2:1 male: female ratio); the majority were general/family medicine physicians in private practice. Forty-nine per cent of the responding physicians were mostly prescribing generic brands willingly, indicating that the cheaper cost of generic substitutes was a significant factor for this trend. There were doubts about whether bio-equivalence of a generic was equitable to therapeutic equivalence to innovator drug. Additionally, 33% of the physicians were able to identify at least one case in the past year of clinical problems with generic substitutes that they perceived would not have occurred with the innovator. It is concluded that while the amendment to the Pharmacy Act encourages the substitution of generics in preference to innovator brands, more emphasis should be placed on improving physician confidence in the therapeutic equivalence of generics.

Sustituciones Genéricas: una Encuesta del 2005 Sobre la Aceptación y Percepciones de los Médicos en Jamaica

M Gossell-Williams

RESUMEN

En Jamaica, la enmienda de 1993 a la Ley de Farmacia permite al farmacéutico ofrecer a los pacientes sustituciones genéricas para las marcas innovadoras. Sin embargo, había reservas entre los médicos acerca de la implementación de esta política. El éxito de la enmienda puede ser influido por la confianza de los médicos en la equivalencia terapéutica de los genéricos, sobre todo porque la ley también permite a los médicos indicar en las prescripciones que no ha de usarse "ninguna sustitución". El objetivo de esta investigación fue examinar las actitudes actuales de los médicos hacia el uso de sustituciones genéricas. Se distribuyeron cien encuestas por toda la isla entre médicos de distintas especialidades, con puntos en los que se pedía caracterizar sus demografías, y hacer declaraciones específicas a fin de determinar su percepción de los genéricos. Sesenta encuestas regresaron totalmente respondidas (60% de respuesta). La mayoría de los médicos que respondieron eran hombres (proporción 2:1 hombre/mujer); en la mayor parte de los casos se trataba de doctores de medicina general, o de familia que ejercían de forma privada. El cuarenta y nueve por ciento de los médicos encuestados dijeron prescribir principalmente marcas genéricas, indicando por voluntad propia que el menor costo de los sustitutos genéricos era un factor significativo para esta tendencia. Había dudas sobre si la bio-equivalencia de un genérico era equiparable a la equivalencia terapéutica con respecto

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al medicamento de innovación. Además, 33% de los médicos pudieron identificar al menos un caso en el último año de problemas clínicos con los sustitutos genéricos, lo cual según su percepción no habría ocurrido con el innovador. Se concluye que si bien la Ley de Farmacia estimula la preferencia de la sustitución de genéricos por encima de las marcas innovadoras, debe hacerse más énfasis en mejorar la confianza del médico en la equivalencia terapéutica de los genéricos.

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INTRODUCTION

A preference for the use of generics among patients was reported in Denmark, Spain and Norway (1, 2). In Denmark for example, the generic market accounts for an average of 62.3% of market share from the period 1994 to 2004. In the United Kingdom and other European countries, the cost-saving benefits of generics substitution are significant (3–5). Similar findings were also reported in a 2002 survey conducted in the United States of America (USA), among consumers 45 years and older, where 24 per cent of the respondents said they were not able to afford a prescription medication when there was no generic available. Therefore in developing countries, like Jamaica, generics can also have positive influences on therapy because of their generally cheaper cost. Presently, the Standards and Regulation Division of the Ministry of Health which is responsible for the registration of all pharmaceuticals has approved generic brands from countries such as Canada, USA and India.

In Jamaica, amendments in 1993 to the Pharmacy Act mandated pharmacists to offer all patients substitution of innovator brands of prescription drugs with less expensive generic brands, thus allowing the patient to choose (6). Similar policies were introduced in some European countries such as Denmark, the Netherlands and France.

Along with the authority given to pharmacists, the 1993 amendments to the Pharmacy Act also allowed physicians to request "no substitution" of innovator brand by generic or one generic brand by another brand (6). In Denmark, where a similar exception is allowed, a 2005 survey showed that generics dominated the market, as prescriptions forbidding generic substitution accounted for only 6.1% of the prescriptions authorized. A similar system introduced in France in 1999 was however not successful, as generics account for only 3–4% of the market and was possibly influenced by the resistance of physicians in France to generic substitution (7).

In 2003, a "Jamaica Gleaner" newspaper article reported that both physicians and pharmacists expressed dissatisfaction with the generic substitution mandated by the Pharmacy Act, suggesting that generics were plagued with many incidences of therapeutic inequivalence (8). Similar suggestions of therapeutic inequivalence were reported in other countries (7, 9). The aim of this investigation was to examine the current attitudes of Jamaican physicians island-wide towards generic substitution and to evaluate the problems they have encountered with use of generics.

METHODS

The Medical Council of Jamaica is responsible for registering all physicians in Jamaica. As of December 2005, the register had 2679 physicians on record (oral communication with Council). Inability to access the contact numbers of physicians on this registry resulted in the use of the local telephone directory for contact numbers. Contact numbers were taken from the yellow pages of the local telephone directory of 2005 issued by Cable and Wireless which listed the addresses and telephone numbers of approximately 350 physicians, either as individual or associated with group practice and distributed islandwide. Using the local telephone directory, physicians were contacted through random selection from this directory, ensuring distribution across the three counties. A total of 100 physicians were contacted (2% of numbers registered with the Medical Council of Jamaica).

The questionnaires were distributed to physicians by email (n = 18) fax (n = 14), by hand (n = 30) or completed over the phone (n = 38) in a period of two weeks in December 2005. The questionnaire designed for this study was adapted from a similar survey conducted by the University of Mississippi. Items in the questionnaire included demographic information (gender, age, medical speciality and location of private practice). The average number of prescriptions authorized (written and phoned in) per day was also recorded. Physicians were asked to indicate the percentage distribution of these prescriptions between generic and innovator drug. The questionnaire contained specific statements aimed at determining their attitudes towards generic substitutions with the choice of responses being: strongly disagree, disagree, no view, agree and strongly agree. The data from the questionnaire were collected and analyzed to determine the overall opinion of the responding physicians.

RESULTS

Characteristics of the responding physicians

Of the total number of questionnaires distributed island-wide, 60 were returned completed, giving an effective response rate of 60%. The responders were mostly male and were mostly younger than 50 years old (Table 1). Most of the physicians sampled were in private practice (n = 47). In terms of medical speciality, they were mainly family/general physicians (Table 1). The most successful method of collection was completion of questionnaire by phone, while email and fax gave low return rates.

Table 1: Demographics of the responding physicians (n = 60)

	Number	% of Responders
Questionnaire distribution (n = 100)		
By hand (n = 30)	15	25
By Phone (n = 38)	38	63
By email (n =18)	6	10
By Fax (n =14)	1	2
Gender (n = 60)		
Male	41	68
Female	19	32
Age distribution (n = 60)		
39 yrs or less	23	38
40–49 yrs	19	32
50–59 yrs	3	5
60 yrs or more	5	8
Medical Speciality (n = 60)		
General/Family	33	55
Obstetrics/gynaecology /child health	17	28
Internal medicine	2	3
Others	8	13
Average Number of prescriptions authorized daily (n = 57)		
10 or less	14	25
11 to 20	26	46
21 to 39	15	26
40 or more	2	5
Location of private practice (n = 50)		
Surrey	23	46
Cornwall	9	18
Middlesex	18	36

Physician prescribing practices

Of the physicians in the sample, most were authorizing (written and phoned) between 11 to 20 prescriptions on average per day (Table 1) and these prescriptions were mainly for generic substitutes of innovator brands (Fig. 1). Further examination showed that 18% of family/general medicine specialists, 13% of paediatricians and 40% of the obstetricians/gynaecologists had a preference for authorizing prescription of the innovator brands.

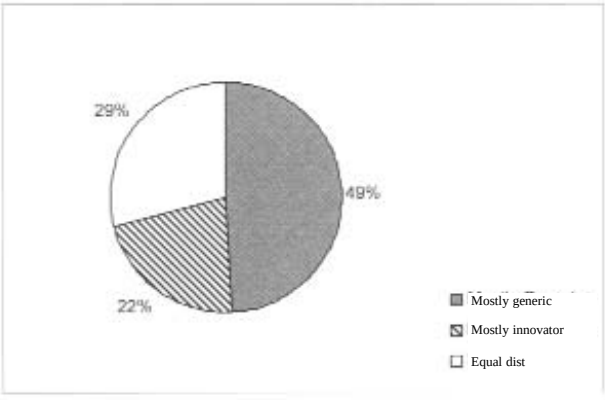

Fig. 1: Chart showing the trend of responding physicians in authorizing prescriptions. Most of the responding physicians had a preference for prescribing generics.

Physicians' attitudes towards generic substitution

The physicians were asked to state whether they strongly agreed, agreed, disagreed, strongly disagreed or had no view to eight statements evaluating their attitudes toward generics (Fig. 2). When they were asked whether they had to support

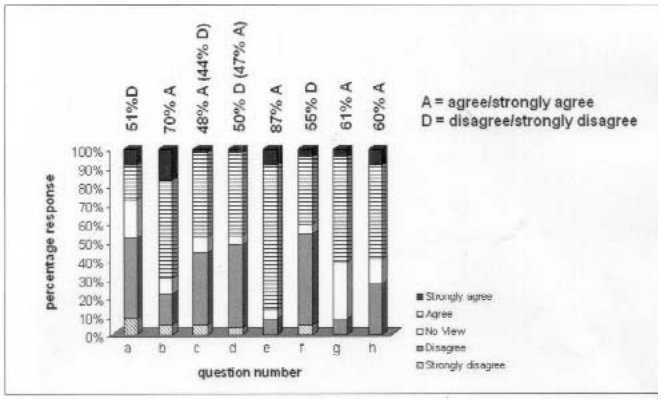

Fig. 2: Graph showing the responding physicians' perceptions of generic substitution. Bars represent the percentage responding to each of the choices (strongly disagree, disagree, no view, agree or strongly agree). Above bars are percentage values with the largest proportions; for statements c and d, the second largest proportion is also given in brackets.

a. *In order to keep patients, I have to support generic substitution*:
b. *The price difference between generic and innovator brand products is often so great. I feel I must offer patients products with generic substitute.*
c. *All generics that are rated as bioequivalent can be considered therapeutically equivalent with the brand name products.*
d. *There is no real difference between most innovator brand name products and their generic.*
e. *I willingly support generic substitution for brand name prescription products.*
f. *I generally prescribe the innovator brand name and leave it to the pharmacist to discuss the generic alternatives.*
g. *Few physicians are opposed to the use of generics today.*
h. *Therapeutic failures are a serious problem with some generic products.*

generic substitution in order to keep patients, the majority of the responding physicians disagreed (Fig. 2a). The majority of the physicians agreed that the cost of the generics was a major factor in their prescribing choices (Fig. 2b).

When physicians were asked whether generics that are bio-equivalent were therapeutically equivalent to the innovator, there was equal distribution between agreement and disagreement with this statement (Fig. 2c) suggesting lack of confidence in the performance of the generics available in Jamaica. This lack of confidence may also explain the similar distribution of the responses relating to whether there was no real difference between generic and innovator brands (Fig. 2d).

The majority of the physicians responding to this survey indicated a willingness to prescribe generics (Fig. 2e) including those physicians who noted clinical problems with specific generics. Most of the responding physicians felt confident in their knowledge of generics and were not leaving it solely to the pharmacists to offer generic substitutes to the patients (Fig. 2f). With further analysis, it was observed that the responding physicians who were authorizing mainly innovator brands (n =12) were also more likely to leave the discussion of generic alternative to the pharmacists (eight agreed/strongly agreed *versus* three disagreed/strongly disagreed; one with no view to the statement). However, the responding physicians authorizing mainly generics (n = 28) were more likely to be active in the decision to use a generic brand (six agreed/strongly agreed verses 21 disagreed/ strongly disagreed).

The majority of the responding physicians agreed that few physicians are opposed to the use of generics (Fig. 2g), although they agreed that there were therapeutic failure issues with some of the generic brands available (Fig. 2h).

Physician experience with generic drug therapy failure incidence

Physicians were asked whether in the past year they had any cases of clinical problems (therapeutic failure, adverse reactions) experienced by their patients that they believed would not have occurred with the innovator drug. Twenty of the responding physicians (33%) reported clinical problems with specific generics with most of the clinical problems being associated with anti-infectives (Table 2). However despite these occurrences, an examination of this subgroup of physicians showed that there was still a preference for writing generic prescriptions (Fig. 3).

Table 2: List of generics reported by responding physicians as having clinical problems that they believe would not have occurred if the brand-name product was used.

Generic drug mentioned	Number of mentions	Outcomes
Metformin	7	Additional office visits, cramping and diarrhoea Additional laboratory diagnosis, emergency room visit, hospitalization, change prescription
Salbutamol inhaler	3	Additional office visit, increase dose, emergency room visit, change prescription
Beclomethasone	1	Additional office visit, change prescription
Amoxillin-clavulanic acid	2	Additional office visit
Chlorpropamide	1	Additional office visit, change prescription
Amlodipine	3	Additional office visit, increased dose, change prescription, emergency room visit, hospitalization
Fluconazole	3	Additional office visit, change prescription,
Lansoprazole	1	Change prescription
Norfloxacin	1	Change prescription
Ciprofloxacin	2	Additional visit, change prescription
Timolol	1	Additional visit, increased prescription, blindness
Simvastatin	1	Additional visit, increased prescription dose, changed prescription, hospitalization
Clotrimazole	1	Increase dose, change prescription
Diclofenac	1	Increased dose
Furosemide	2	Additional office visit, increased dose, emergency room visit, hospitalization
Piroxicam	1	Hospitalization
Enalapril	2	Additional office visit, change prescription, emergency room visit
Ranitidine	2	Additional office visit, increased dose changed prescription
Terazosin	1	Not specified
Terbenafine	1	Additional office visit, change prescription
Metronidazole	1	Additional office visit, changed prescription

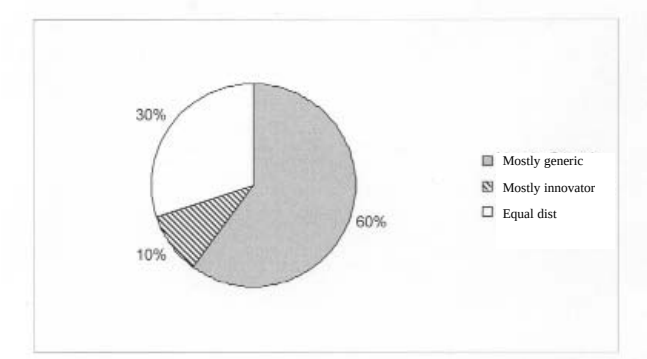

Fig. 3: Chart showing preference of the authorized prescriptions among physicians reporting clinical problems with generics (n = 20). Even though these physicians reported specific complications, they were still mainly prescribing generics.

DISCUSSION

The data collected from this survey suggested an island-wide acceptance of generics by responding physicians. Most physicians were comfortable with having the choice and were authorizing both innovator brands and generic substitutes. The responding physicians were mainly authorizing prescriptions of generic substitutes despite the concerns the responders had in their therapeutic equivalence. This observation is different from the findings of a 2005 survey conducted in France (where a similar generic substitution policy exists) which reported that physicians were not likely to prescribe generics over innovator drugs as they were concerned with adverse effects (7). It was noted that of the specialities represented in this present study, obstetricians/gynaecologists were the most likely to show a preference for authorizing innovator brands. The impact of such groups on the success of the amended Pharmacy Act should be examined.

The cost of generics *versus* the innovator drug was shown to be a major factor in the acceptance of generics by physicians. This was also noted from the comments of some of the responding physicians. For example, two physicians indicated that for a patient being treated for one or more chronic illness, the long-term financial burden might compel the physician to prescribe the generics. A few physicians commented that where there is no significant difference in the cost between the generic and innovator brand, there might be a preference for prescribing the innovator brand. These comments thus point to other factors that influence physicians' prescribing practices that were not examined and should be considered in an extension of this study.

The prescribing choices made by physicians occurred without fear of losing patients because of brand preference. It is important to note that physicians with preference for prescribing generics felt adequately informed to authorize the prescription of generics directly rather than leaving the decision completely to the patient and their tending pharmacist. However, physicians preferring innovator brands were more likely to allow the pharmacist to discuss the alternatives with their patients.

Although it is accepted that bio-equivalence is the main factor in therapeutic equivalence, the Food and Drug Administration (of the USA) defined other important factors of therapeutic equivalence, including safety profile, efficacy and use of good manufacturing practices. In this survey, it was found that whether physicians had a preference for generics or innovator brands, the majority were aware that some generic substitutes being marketed in Jamaica were associated with therapeutic failures and unexpected adverse effects and therefore raised doubts about therapeutic equivalence to the innovator. This finding is however limited, as the survey only assessed the perception of physicians rather than a quantifiable examination of the extent of the problem. Additionally, although the majority of the responders agreed (and strongly agreed) that there were therapeutic failure issues with generics, only thirty-three per cent were able to give specific examples. It can however be inferred that since the physicians reporting specific examples believed these complications would not have occurred with the innovator brand, physicians would benefit from more information on the registration and monitoring process of generic brands in Jamaica. Providing this sort of support to physicians may reduce doubts about the bio-equivalence and therapeutic equivalence of generics to innovators.

Further examination of the specific complication reported by physicians with generic substitutes suggests that although failure may be related to therapeutic inequivalence, it is important to recognize that anti-infectives (antifungal and antibacterials) accounted for most of the reported therapeutic failures. The main question to be asked therefore is whether the reported failures were due to micro-organism resistance rather than therapeutic inequivalence. One physician reported that extending the treatment period cleared the infection. Extension of therapy with generic (or innovator drug) is one standard method of overcoming micro-organism resistance to drug therapy. However, the number of complications reported in this survey, as well as the ambiguity surrounding the causal association of complications suggests an important need to ensure tight monitoring of generic substitutes, especially with the government mandated substitution policy that favour cost.

One limitation of this survey involved access to the physicians; while the local directory does not list all the physicians registered by the Medical Council of Jamaica, it covers physicians island-wide, currently practising and therefore allowed random selection of physicians from all regions. However, this survey is the first documented report analysing the attitudes of physicians towards the use of generic substitution in Jamaica since it became mandatory for pharmacists to always offer patients the cheaper generic substitutes available and therefore can provide useful information for directing policy decisions.

In conclusion, while physicians are overall willing to accept generic substitution, it is recommend that greater emphasis be placed on programmes to increase the confidence of physicians in the therapeutic equivalence of all available generic substitutes. Continuing medical education programmes focussing specifically on issues related to generic brands should be considered. Educating physicians on the actions of the Ministry of Health in ensuring the quality of all pharmaceuticals, which is done with the assistance of other government organizations, such as "The Jamaica Bureau of Standards" and the "Caribbean Regional Drug Testing Laboratory" can assist in reassuring physicians that the performance of generics are being monitored. Additionally, the Ministry of Health provides all physicians (and other stakeholders) with a method of reporting therapeutic failure and adverse events that occur with all drugs through the standardized drug monitoring form.

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