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How do general practitioners, pharmacists and patients evaluate the substitution system for prescription in Denmark?

Sune Rubak, Marie-Louise Elkjær Andersen, Jan Mainz, Peder Olesgård, Torsten Lauritzen

Aim/Objectives: Evaluation of how the substitution system has been implemented, how it was assessed by the general practitioners (GPs), pharmacists (PHs) and patients, and clarification of benefits and problems related to the system.

Methods: The study was based on specific questionnaires to GPs, PHs and patients. The questionnaires were based on qualitative interviews with all three groups and afterwards validated and pilot tested.

Results: 80% of 300 GPs, 72% of PHs and 82% of 105 patients responded. The study showed that 84% of the patients were satisfied with the system. Of the patients, 83% had tried a substituted drug previously. Of these, 4% had experienced various side effects, and 7% had experienced a weaker effect from the substituted drug. One case of adverse medical treatment as a consequence of substitution was reported. The study showed that 61% of GPs were dissatisfied with the system and assessed that it should be abolished.

Conclusions: The GPs' reasons for suggesting that the system be abolished were that the system was incompre-

hensible, badly introduced and created an extra workload. Half of the PHs were dissatisfied with the system, primarily due to the excessive workload imposed. In spite of this, about half of the PHs wanted the system to be continued, because the overall intention was good, in terms of getting the prescribed drug as cheaply as possible for the patient. Nearly all statements from the patients showed that overall the patients thought the benefits greater than the disadvantages in the system. All GPs and nearly all PHs were of the opinion that analogue substitution (substitution between drugs with the same effect obtained by different means) was medically unjustifiable, did not have potentially desirable effects, and should therefore not be introduced.

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Introduction

In 1997 a new prescription system was introduced in the Danish healthcare system.¹ Before this there were no rules about how the general practitioner (GP) should prescribe generic drugs. It was decided to introduce the substitution system, because the expenses related to prescribed drugs in Denmark had increased over the last decade. So there was a potential to cut down on expenses. In the new prescription system the pharmacist (PH) was obliged to substitute for a cheaper prescription, either generic (G-substitution, synonymous drugs) or original (O-substitution, identical drugs parallel-imported under different names), unless the GP specifically indicated that substitution was not allowed.^{2,3}

The following endorsements could be written on the prescription:

- No-S: PH may not substitute the prescription in any way.

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- No-G: PH may not perform G-substitution, but can perform O-substitution.
- No-O: PH may not perform O-substitution, but can perform G-substitution.

Both GPs and PHs have criticised the system because the drugs may deviate in shape, form and colour, which may cause confusion for the patients. Especially for elderly and psychiatric patients the system may increase the risk of poor compliance, incorrect medication, confusion and mistrust in the GPs.^{4,6} At the same time it has been indicated that the system has imposed an increased workload on GPs and PHs because of the extra questions from the patients as well as the demand for more control and larger storage of drugs. In general it has been the assumption that the GPs automatically use the 'No-S' endorsement on a large scale to avoid these problems, which can undermine the substitution system for prescription.

The purpose of this study was to evaluate how the substitution system has been implemented, as well as how it was assessed by the GPs, PHs and patients in order to identify benefits and problems related to the system.

Material and methods

The study was conducted in 1999. A random sample of 10% of all GPs and 25% of all PHs in Denmark were invited to participate. The GPs (n=300) were randomly chosen from the database of the College of General Practitioners. All GPs were randomly selected geographically and stratified on age, sex, seniority, practice in a rural or city setting, size of patient list in order to reflect the Danish GP population. The GPs were asked to answer a questionnaire about the substitution system and a questionnaire about age, sex, seniority as a GP, size of practice, etc.

The PHs (n=75) were randomly chosen from the database of the pharmacists' organisation. All PHs were randomly selected geographically and stratified on age, sex, seniority and size town/number of inhabitants in the area of the pharmacy to reflect the Danish PHs. Specific questionnaires to GPs and PHs were developed from qualitative interviews with GPs and PHs and were pilot tested on a group of GPs and PHs before the study. The final questionnaires were mailed to the study participants, and after 14 days reminders were sent out. The patient study was conducted in 1998/99. Patients were consecutively included over five random days. A total of 105 consecutive patients attending at the pharmacy in Grenaa (a provincial town with 20,000 inhabitants) were asked to participate in the study. The patients invited to participate in the study had just received a drug from a prescription, which had been substituted. The inclusion criteria were: age 18 or older, able to speak, read and understand Danish, and they should have a prescription from a GP. A validated and pilot tested questionnaire was handed out to the patients. After three to four weeks, the patients who agreed to participate were interviewed by telephone.

Results

Response rate and background information about GPs, PHs and patients are shown in table 1.

Satisfaction and credibility

GPs', PHs' and patients' satisfaction with the substitution system is shown in table 2. Of the GPs, 64% found the introduction to the substitution system poor. Regarding the three endorsements (No-S, No-G, No-O) 33.9% did not understand the meaning of No-S, 49.4% did not understand No-G, and 59.4% did not understand the meaning of No-O. GPs', PHs' and patients' opinions of how the system would affect GPs' credibility are shown in table 3.

Electronic Data Processing system (EDP) and substitution system

Of the GPs, 56.9% stated that their EDP automatically made the endorsements of substitution with 85% choosing No-S (no substitution), 15% No-G (can substitute with identical parallel-imported drugs), and 0% No-O (can substitute with synonymous drugs). Reasons for this were: quick and easy (96.3%), support for the drug company who developed the drug (95%), precise medication for the patient (77.9%) and to avoid confusion for the patient (77.1%). PHs stated that 30% of prescriptions had the endorsement No-S (non-substitution).

The substitution system and related problems

Of the GPs, 67.4% indicated an increased workload of 10 min/day. Two-thirds of the PHs found an increased workload of 50 min/day, spending 30 min/day on control of substituted prescriptions and 20 min/day on providing additional patient information.

Table 1. Information about general practitioners, pharmacists and patients.

General practitioners	
Response rate	79.9%
Average age	50 years
Sex-ratio (m/f)	3/1
Average seniority as GP	15 years
Geographical dispersion	
• Country	16%
• City	50%
• Provincial	34%
Pharmacists	
Response rate	72.1%
Average age	51 years
Sex-ratio (m/f)	1/1
Average seniority as pharmacist	26 years
Patients	
Response rate	84.0%
Average age	64 years
Sex-ratio (m/f)	1/1
Average number of prescribed drugs/week	3 drugs/last week
First time experienced drug substitution	55% of patients

Table 2. Satisfaction with the substitution system.

	N	Satisfaction (percentage with 95% confidence interval)					
		Dissatisfied		Neutral		Satisfied	
Patients	88	7	(3-15)	8	(4-18)	84	(74-91)
GPs	239	61	(53-69)	26	(18-34)	13	(5-21)
PHs	54	50	(42-58)	23	(15-31)	27	(19-35)
Patients as taxpayers	88	2	(0-8)	14	(7-23)	84	(74-91)
GPs as taxpayers	239	18	(10-22)	44	(36-52)	38	(30-46)
PHs as taxpayers	54	11	(3-19)	29	(21-37)	60	(52-68)
GPs' opinion of patient satisfaction	239	50	(42-58)	37	(29-45)	13	(5-21)
PHs' opinion of patient satisfaction	54	14	(6-22)	37	(29-45)	49	(41-57)
PHs' opinion of GP satisfaction	54	70	(62-78)	21	(13-29)	9	(1-17)

Table 3. General practitioners' credibility.

How will the substitution system affect the GPs' credibility in relation to the patient?

	N	Opinion (percentage with 95% confidence interval)					
		Positive		Neutral		Negative	
GPs	239	1	(0-8)	43	(35-51)	56	(48-64)
PHs	54	2	(0-10)	62	(51-69)	36	(28-44)
Patients	88	8	(4-18)	90	(81-98)	2	(0-10)

Of the GPs, 94.2% and all PHs answered that 6-10% of substituted prescriptions caused patient confusion, problems with other side effects and adverse medication. Furthermore the GPs estimated that 15% of substituted prescriptions caused complaints from patients. The PHs stated that patients often had problems with more difficult packaging (72.4% of PHs had experienced this within the last four weeks), more difficulty in dividing the tablets (54.5% of PHs had experienced this within the last four weeks) and different taste for the worse (38.5% of PHs had experienced this within the last four weeks). Of the patients, 7% reported the experience that the substituted drug had less effect compared with the prescribed drug, 4% reported the experience of more side effects with the substituted drug, 9% of the patients stated that they had contacted their GP, and 5% their local pharmacy with questions about the substituted drug and the substitution itself.

A total of 27% of the GPs and 41.9% of the PHs had experienced adverse events in medication related to approximately 5% of substituted prescriptions. Moreover, 4.6% of the GPs and 7% of the PHs had experienced life-threatening situations related to the substitution system within the last four weeks. As an example, a patient stopped taking the drug because it had a different name and shape. Another patient took a double dose because of the assumption that both 'the old and the new' drug should be taken. One patient in the study had experienced a potential life-threatening situation because the person had taken a smaller dose of the medication than prescribed.

The assessment of GPs, PHs and patients as to whether the system should continue is shown in table 4.

Discussion

This study was conducted two years after the introduction of the substitution system. The statements and conclusions are therefore not an expression of acute problems due to the substitution system, but a reflection of how the system worked in 1999. The response rates of the study are considered to be very satisfactory. The GPs indicated that the introduction for the substitution system was inadequate. Furthermore the GPs did not understand the three endorsements of the system in spite of pre-information.^{2,3} This was also shown in a previous study.⁷ In an earlier Danish study it was concluded that to obtain an optimal substitution system, a clear structure and management and a thorough introduction to the users were essential.⁴ The GPs lack of understanding is probably due to insufficient information, but also uncertainty with regard to the use of endorsements. This is supported by the finding that the two endorsements (No-G, No-O) are hardly ever used.

In general the PHs and GPs were dissatisfied with the substitution system. A previous study concluded that 78% of GPs were dissatisfied, while only 8% were satisfied.⁷ The GPs appraised that the patients were dissatisfied with the system, which conflicts with other studies in both Denmark and Europe, where patients evaluated the system positively.^{4,8-12} It is also in variance with the patients' positive evaluation in this study.

Table 4. The future of the substitution system.

	N	Opinion (percentage with 95% confidence interval)					
		Yes		No		Don't know	
Continue substitution system?							
• GP	239	32	(24-40)	44	(36-52)	24	(16-32)
• PH	54	48	(40-56)	37	(29-45)	15	(7-23)
Improve substitution system?							
• GP	239	22	(14-30)	19	(11-27)	59	(51-67)
• PH	54	65	(57-73)	16	(9-24)	19	(11-27)
Analogue substitution system?							
• GP	239	0	(0-8)	99	(92-100)	1	(0-8)
• PH	54	11	(3-19)	89	(81-97)	0	(0-8)

A majority of the GPs stated that the system resulted in a poor overview and control of patient medication, loss of their rights of prescription and less credibility towards the patient. This is in contrast to the fact that almost all GPs accepted a responsibility for an economically acceptable drug treatment both for patient and society. This can be a reason for the dissatisfaction with the system. In this context it is also of interest that previous studies in Denmark and Europe have shown that half the GPs do not believe that the introduction of a substitution system results in the intended and expected cut-downs on the expenses for medication, and that it is the GPs' impression that the system has a negative effect on their credibility towards the patient.^{7,13,14} An important message from this study is that almost all patients did not think that the substitution system affected the GPs' credibility at all.

The study revealed that half the GPs avoided substitution through their EDP system. The National Department for Medical Drugs found that in 1997, 25% of the GPs chose No-S.¹⁵ This underlines the dissatisfaction of the GPs and raises questions about the effect of the system.

The increased workload for the GPs due to substitution has also been reported by others in Denmark and Europe.^{7,12} The increased workload seems to be due to more contacts with confused patients, pharmacies, elderly homes, etc. In earlier studies both GPs and PHs had experienced patient confusion because of substitution.^{5,7,12,16} Other studies have indicated that GPs experienced similar problems and risks, which lead to lack of compliance, confusion and adverse events in medication.^{12,16} Substitution increased the risk of adverse events in treatment, especially for the weakest patients who often get their drugs by postal service without contact with the pharmacy.⁶ In this study only one patient with the wrong medication caused by substitution was identified. This low number may be due to the fact that only patients able to attend the pharmacy were included. In Denmark there has been an increased number of hospital admissions because of wrong medication.¹⁷ A few studies within Europe have doubted if substitution

in all cases actually results in equal absorption, distribution, excretion and effect from the drug.^{18,19}

The GPs and PHs did not find that the effectiveness of the substitution system was in proportion to the increased workload imposed on them without extra resources. Nor did they find that the system had the desired and expected socioeconomic results. In contrast the patients assessed the system positively both as patients and as taxpayers, which indicates that they did not think that the related problems were significant compared with less expenses for drugs. In several European countries substitution has caused similar problems.^{12-14,16,20}

In conclusion it must be emphasised that an evaluation of continued substitution system must clarify whether it is the opinion of the professionals in the healthcare system (GPs and PHs) or the opinion of the patients that decides the direction of the system. Also, a thorough socio-economic evaluation of the substitution system is lacking. Does the actual retrenchment from the system counterbalance the increased workload and use of resources of GPs and PHs? How high are the costs of mistaken medication and extra hospital admissions due to the substitution system? And finally introduction of analogue substitution (substitution between drugs with same effect obtained by different means) should be delayed until the above questions have been answered, especially in the light that analogue substitution was deemed medically unjustifiable, and did not have potentially desirable effects and should therefore not be introduced. The GPs want to maintain their free rights of prescription and the GPs stated that analogue substitution would change the fact that all the patient's medical treatment should exclusively be a doctor's decision, which was unacceptable. A majority of PHs agreed with all of this. ■

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morale and possibly negative feelings about work which are attributable to broader social and cultural factors.¹² Certainly, the vague and amorphous nature of the stress category itself means that conceptualisations appear to range from relatively minor frustrations and low morale to extreme anxiety and distress likely to induce physical illness. The qualitative data show that informants' descriptions of stressful experiences seems to suggest dissatisfaction rather than severe stress-related anxiety.

Conclusion

In conclusion, the image of general practitioners and other members of the practice experiencing elevated work-related stress, according to this evidence, might be accurate if a broad definition of stress is adopted. The evidence suggests that working conditions in general practice can lower morale in some practices and make some people unhappy in their work although there was little evidence that this leads to more serious psychological or physical health problems. This is not to suggest that practice staff were not extremely busy, or, that job satisfaction and morale could not be improved, only that most informants appeared to be coping with their work and did not expect their physical or psychological health to be impaired by their job. It is also clear that policies aiming to ameliorate the dissatisfaction and low morale in general practice should particularly target practice managers specifically focusing on their training and ensuring that they have a clearly defined and adequately supported managerial role. ■

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