

Complications and side effects: a problem in general practice?

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Abstract. On basis of secondary analysis of data obtained from the 'Dutch National Survey of Morbidity and Intervention in General Practice', we tried to gain insight into the nature and extent of iatrogenic illnesses in general practice. In this registration project 386,000 contacts of patients with 161 GP's have been recorded, using the International Classification of Primary Care (ICPC). We confined ourselves to 'side effects of medication' and 'complications of medical treatment'. It appears that in two percent of all contacts the GP has made one of these two diagnoses, or has considered these. On average, the patients concerned suffered twice more often serious invalidating or danger of life.

Herewith these two groups of iatrogenic harm constitute an important problem in general practice.

1. Introduction

General practitioners make errors, patients can become more ill on account of treatment [1]. The extent and seriousness of this problem is unknown, for hardly any research is done on errors and iatrogenic harm in general practice [2].

Therefore we want to initiate an investigation in order to obtain insight into the prevalence of harmful aspects of GP-care. We will do so on basis of a secondary analysis of data obtained from a large scale registration project of morbidity in general practice, the 'Dutch National Survey of Morbidity and Intervention in General Practice'.

Our main questions were:

- Which aspects of iatrogenic harm can be quantified by means of a secondary analysis of the 'National Survey' data?
- How often is a GP, in his daily practice, confronted with these quantifiable aspects of iatrogenic harm?
- What are the characteristics of the patients concerned?

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2. Methods

2.1. *The National Survey*

We made use of data from the 'Dutch National Survey of Morbidity and Intervention in General Practice', a registration project carried out by the Dutch Institute for Research of Healthcare (Nivel) [3, 4]. In the 'National Survey', for a period of three months, all patient-contacts in 103 practices with 161 GPs and 335,000 patients have been registered using an extensive version of the International Classification of Primary Care (ICPC) [4].

The GPs have been selected by means of an a-select, non-proportional, stratified random sample from the register of all active GPs in The Netherlands.

To acquire an even spread over the seasons, the whole year has been subdivided into four periods of three months each. The practices have been equally distributed over these four periods. On a pre-structured form the following information of each contact was recorded:

- data about the contact (length, consultation/home-call, first contact/following contact);
- complaints (Reason For Encounter, RFE) and diagnosis(es), and the certainty about it. Three different RFE's and diagnoses could be registered at the most;
- to which extent the GP considered the complaint to be invalidating or endangering the patients life;
- any underlying illnesses and problems, including possibly operation or hospitalization;
- treatment, medication, referrals and if relevant the attending specialist;
- the patient's personalia.

The GPs completed these data. On basis of the ICPC, fieldworkers encoded the complaints (RFE) and the (probability) diagnoses, as the GPs had reported them.

In the ICPC two concepts determine part of the iatrogenic harm, viz.: 'side effects of medication' and 'complications caused by medical treatment'. Both these concepts refer to the result of the care rendered; they describe an undesirable outcome of care, caused by the prescribed medication as well as by the medical treatment. Concepts, as for instance 'error', referring to an unfavourably judged process of care, can not be measured by means of this ICPC registration project [5]. Therefore it remains unknown, whether in the process of care rules have been broken.

In the 'National Survey' the ICPC-categories 'side effects' (A-85) and 'complications' (A-87) are divided into three sub-categories [4]:

The code A-85, labelled 'adverse effect medical agent proper dose' has been differentiated by the 'National Survey' into:

- A-85.1:** side effect medication: allergy;
- A-85.2:** side effect oral contraception (pill);
- A-85.9:** side effect medication: other.

The code A-87, labelled 'complication surgery/medical treatment, X-ray' has been differentiated into:

- A-87.1:** complications medical treatment: hemaetome;
- A-87.2:** complications medical treatment: wounds;
- A-87.9:** complications medical treatment: other.

In the 'National Survey' 386,000 contacts of patients with GPs or practice assistants have been registered. In the following we only give the contacts with GPs. The outcome is represented at contact-level, not at episode-level. The data have been standardized and generalized for all of the Dutch population.

3. Outcome

3.1. Contacts

Table 1 shows that GPs in The Netherlands in a period of three months consider in over 236,000 contacts, the diagnosis 'side effect'/'complication' or actually make this diagnosis. In nearly 125,000 contacts the diagnosis is 'other' (A-87.9).

3.2. Side effects medication A-85

It is impossible to trace which medicines cause side effects most frequently. For it is impossible to establish which medicine caused the side effects discussed at the contact. One can only determine which medicines have been prescribed at the contact (or previous contact), when the 'side effect' was mentioned. Besides, it proved to be impossible to establish which diagnoses go with these side effects. For it is not evident that the registered diagnosis is a description of the side effect, or that the treatment of this diagnosis resulted in the side effect. For instance: in case of an allergic reaction to a medicine, most frequently the concurrent diagnosis 'urticaria' is made. The question is, however, whether 'urticaria' was caused by the medication, or by the diagnosis, causing a complication on account of the treatment (e.g., sleepiness)? We cannot calculate how many women, using the 'pill', experience side effects, because the registration period only lasted three months and the pill is often supplied for six months, sometimes three months. Therefore we cannot figure out the denominator.

More often than men, women report 'allergies' (61.4%) and 'other side effects caused by medicines' (67.2%). There proves to be a significant relation between age and reporting side effects; the older, the more side effects have been registered. In respectively 24.6% (allergy) and 42.9% (other) of the contacts, when the GP makes or considers the diagnosis 'side effects', the patients are 65 years or older.

Table 1
Number of contacts in three month in the Netherlands, when GP considers, or makes as one of the (possible) diagnosis(es): A-85 or A-87

	Number of contacts:		Percentage of all contacts in Netherlands
	'National Survey'	Netherlands	
Side effects medication			
A-85.1 allergy	412	19,131	0.16%
A-85.2 pill	591	22,974	0.20
A-85.9 other	1495	56,243	0.48+
Sum of A-85 side effects	2498	98,348	0.83
Complication medical treatment			
A-87.1 haematome	49	1,428	0.01
A-87.2 wounds	294	11,538	0.10
A-87.9 other	3260	124,751	1.06+
Sum of A-87 complications	3603	137,717	1.17
Total sum of side effects and complications	6101	236,065	2.00
Sum score for GP-contacts in Netherlands in three months		11.779,650	100%

Table 2
Top-10 concurrent diagnoses when treatment resulted in 'other complications' (percentages)

1	hernia nuclei pulposi	4.4%
2	other complications	3.8
3	malignant neoplasma mamma	2.9
4	stroke	2.3
5	malignant neoplasma colon	2.0
6	hip-complaints	1.8
7	coronary sclerosis	1.5
8	knee complaints	1.5
9	other musculo skelet. dis.	1.4
10	pernicious anaemia	1.2

Table 3
Extent of danger of life and invalidation

The extent of danger of life in contacts concerning complications or side effects, in percentages								
	Nat. Survey Sum	A-85/87 combined	side effects			complications		
			allergy	pill	other	haematome	wounds	other
nearly fatal	0.7	1.0	0.2	–	1.0	–	1.2	1.4
life-danger	0.5	1.5	–	–	1.8	–	–	2.0
serious	1.6	3.6	2.1	–	3.7	6.1	3.7	4.4
slight	3.1	5.8	3.8	1.0	4.9	15.0	3.7	7.5
harmless	61.7	77.4	74.9	92.9	75.5	67.8	76.8	75.8
irrelevant/not completed.*	32.4	10.7	18.9	6.1	13.1	11.1	14.6	9.0
The extent of danger of life in contacts concerning complications or side effects, in percentages								
sev. invalid.	0.9	1.7	0.1	0.4	1.4	2.6	3.4	2.1
moder. ,,	1.3	3.3	0.1	0.4	2.3	0.5	1.9	5.0
limit. ,,	4.1	8.3	3.0	0.7	5.5	14.6	4.6	12.1
slight ,,	7.5	13.5	7.6	15.0	12.1	16.3	10.8	15.0
not invalid.	53.7	62.2	70.7	77.0	65.4	54.9	64.7	56.6
irrelevant/not completed*	32.5	10.9	18.5	6.5	13.3	11.1	14.6	9.2

* The category 'irrelevant/not completed' has not been divided at random over the other categories. These have probably not been completed on purpose, because there is no question of danger of life or invalidation. Therefore this category can not be characterized as 'invalid', since this would imply, that the other categories, when totalled to 100 percent, would be 'valid percentages'.

3.3. *Complications medical treatment A-87*

Among the patients suffering a 'hemaetome' men are over-represented (56.3%). Over forty percent of these patients is 65 years or older (40.2%). Approximately a quarter of the patients have been previously hospitalized for observation or surgery: 20.5% have been operated on and 4.7% need post operational care following hospitalization.

For the group of patients having wound complications these percentages are comparable: 19.5% have been operated and 7.9% received post-operational care following hospitalization. Females are over-represented (63.4%) and 18.3% of these patients is 65 years or older. The majority is between 45 and 65 years old (40.1%).

25.5% of all patients, diagnosed as having 'other complications of medical treatment' have previously been operated and 9.1% received postoperational care following hospitalization. A third of the patients, examined for complications, is 65 years or older (34.0%); 61.6% is 45 years or older. Women, suffering complications, call upon the GP more often than men (58.0% resp. 42.0%).

Finally, we investigated with which diagnoses these complications occurred. Just as is the case with 'side effects', this proved difficult to trace. The large category 'other complications' excepted: here it is evident that the therapy for the concurrent diagnoses probably caused the complications. In Table 2 the top-10 of concurrent diagnoses is stated. Only regarding 'pernicious anaemia', it is doubtful whether it is the diagnosis, for instance having a stiff, painful arm as side effect of an injection of Vit.B12, or a complication, for instance after stomach surgery. For the remaining part it seems to be diagnoses whereby the complication is the result of the treatment.

3.4. *Seriousness of side effects/complications*

Table 3 shows how GPs assess the extent of invalidation and threat to the patient's life, when during the contact (also) side effects and complications are diagnosed or considered as possible diagnosis. 6.1% of these contacts suffer harm ranging from serious to extremely dangerous, in 26.9% it is a matter of slight to serious invalidation. For comparison the mean sumscore of the 'National Survey' are stated.

4. Discussion

An effort has been made to express, in extent and number, some of the unexpected and undesirable consequences of care presented in general practice. This way it can reveal how extensive the problem is and upon which aspects the prevention of complication and side effects should focus. The registration appears to provide less tangible information than we hoped for: the ICPC-code is not suited for this purpose and an assessment of process and results is difficult to execute. Often it was not clear, whether the registered concurrent diagnosis was a further explanation of the complication or side effect, or clearly a matter of complication or side effect caused by treatment of the concurrent diagnosis.

Notwithstanding the limitations mentioned above, we can draw the conclusion on basis of the outcome that GPs in The Netherlands consider or make the diagnosis 'side effects' or 'complications' in 2% of all contacts. These findings correlate with the outcome of another not quite identical study.

In hospitals in the United States apparently 3.7% of all admitted patients suffer harm because of medical treatment. 14 percent of these patients died (partly) on account thereof [6].

From previous research in general practice it can be deduced that medical complications or side effects of medication constitute the most important motive in 1–3% of the GP-patient contacts [7, 8]. In The Netherlands a GP has an average of 800 contacts per 1000 patients in three months [9]. In a standard size practice, this means approximately 145 patient-contacts per week. So on average a GP considers or makes the diagnosis 'side effects' or 'complications', every one or two days. Therefore it is a frequently occurring problem in general practice [4].

The extent of danger and invalidation, which GPs register in the contacts concerning side effects and complications, is remarkable: the percentages are about twice as high as in all the contacts given in the 'National Survey'. In particular, in the category 'other complications' there is a higher degree of danger and invalidation. However, we do not know whether the side effect or complication caused the danger or invalidation, or the illness itself, with its complications or side effects. Only regarding

'other complications' it is obvious that these resulted from the concurrent diagnoses. These apply to serious illnesses, sometimes followed by drastic therapies. None of these diagnoses are among the 20 most frequent diagnoses in general practice in The Netherlands [4].

The correlation between 'side effect or complication' and age and sex is quite clear. GPs consider or make the diagnosis 'side effect or complication' twice more often in regard to female patients, than male patients. Women have indeed more often contact with GPs than men, but even after making this allowance, women are over-represented. Older people too, are often confronted with 'side effects and complications'. This has also been known from other studies [10].

It seems plausible that the GP often functions as a kind of 'safeguard' for specialized care. In approximately a quarter of the contacts, where the GP considered 'complications caused by medical treatment', the patient had previously undergone surgery. Nearly ten percent of the patients needed post operative care.

Of what the 'side effects' and the 'complications' exactly consisted, is unknown. For purposeful prevention the precise details would have to be known; as it is, we can only draw attention to the fact that iatrogenic harm constitutes a non-negligible problem in general practice and that it involves extensive danger to the patient's life and invalidation.

This outcome indicates that further systematic research into the occurrence of iatrogenic harm in general practice, is urgently needed. Because increasingly more GPs computerize their patient-information, using the GP Information System, and because in this system the coding of complaints and diagnoses is mostly done according to the ICPC, we recommend to develop a module that can be linked with the ICPC. In this module the outcome of the care should be coded in such a way that it can be directly related to diagnoses and care. Data on side effects of medication must be linked directly to the prescribed medication.

In order to achieve an effective and efficient prevention of iatrogenic harm in the future, further study is emphatically recommended. Not in the least because otherwise this will remain a subject that can only be discussed in vague terms.

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