

## ORIGINAL ARTICLE

# Characteristics and expectations of patients with erectile dysfunction: results of the SCORED study

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**In an observational study in men with erectile dysfunction (ED) consulting a general practitioner (GP) or urologist in Belgium, demographics, ED characteristics (including erection hardness score), co-morbidities and treatment expectations were evaluated using a structured questionnaire. In total, 341 GPs and 41 urologists recruited 1492 patients. Most (74%) were untreated and 25% had ED for >3 years. Considering PDE5 inhibitors, erection hardness (89%) and maintenance (92%) were considered 'very important' by most patients. Only 18% of physicians initiated discussion about ED, despite 41% of patients having ≥3 known risk factors. The questionnaire was considered helpful by 81% of GPs and 83% of their patients. Overall, patients are under-diagnosed, and physicians are reluctant to ask about ED. A questionnaire including erection hardness score is useful to facilitate discussion about ED in general practice. Erection hardness and maintenance are more important to patients as compared to fast onset or long duration of action.**

*International Journal of Impotence Research* advance online publication, 17 April 2008; doi:10.1038/ijir.2008.7

**Keywords:** sexual dysfunction; risk factors; cardiovascular risk

## Introduction

Erectile dysfunction (ED) is defined as the persistent inability to attain and/or maintain an erection sufficient for satisfactory sexual intercourse. Although psychological factors can contribute, ED is often caused by organic factors, including atherosclerotic arterial disease, neurological disorders, venous insufficiency, endocrine disorders, injury or operations.<sup>1</sup> Since the approval of sildenafil in 1998, oral phosphodiesterase type 5 inhibitors (PDE5i) have become the first-line therapy providing effective, safe and well-tolerated treatment.<sup>2</sup>

As a result of differences in definitions and methodologies, prevalence rates of ED vary substantially across epidemiological studies. Most studies however support the results of the Massachusetts Male Aging Study, demonstrating an exponential rise of ED with age.<sup>3</sup> The prevalence of moderate to

severe ED increased from 22% in men aged 40–50 years to 49% in men aged 60–70 years. In a population-based study in Belgian men aged 40–70 years, estimated prevalence rates were 10% for severe ED, 25% for moderate ED and 27% for mild ED.<sup>4</sup>

Erectile dysfunction affects the quality of life of patients and their partners, and can be reversed by appropriate intervention with a PDE5i.<sup>5,6</sup> Furthermore, recent studies have emphasized the clinical importance of the vascular pathogenesis of ED by identifying it as an observable marker for cardiovascular risk.<sup>7–9</sup> Many patients are however reluctant to discuss ED with their physicians, and many physicians are still uncomfortable when discussing or evaluating sexual (dys)function. A recent study conducted in 1000 patients in Belgium confirmed that ED is still a taboo topic.<sup>10</sup> Although 72% of urologists and 49% of general practitioners (GPs) stated that they initiated communication on ED, 73% of patients claimed the opposite. As a result of this lack of communication, physicians do not always address patients' expectations adequately regarding treatment goals and differences between oral treatment options, such as onset and duration of action, safety, tolerability or costs. One particularly difficult factor to address is erection hardness,

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Received 12 November 2007; revised 15 January 2008; accepted 6 February 2008

although it is of critical importance in treatment success.<sup>11</sup> In a study involving 1960 men, insufficient efficacy was the main reason (83%) to switch treatment. Moreover, patients were more satisfied with the new treatment because it yielded stronger erections (73%).<sup>12</sup> One simple way of assessing erection hardness is the four-point Erection Hardness Score (EHS),<sup>11,13</sup> and recent studies have shown that even a shift from score 3 (penis hard enough for penetration but not completely hard) to score 4 (penis is completely hard and fully rigid) correlates with statistically significant increases in self-esteem, confidence, sexual relationship and overall relationship (Self-Esteem and Relationship questionnaire) as well as increases in satisfaction, orgasmic function, sexual desire and intercourse satisfaction (International Index of Erectile Function, IIEF).<sup>11,14</sup>

The Stimulate Communication On Rigidity in Erectile Dysfunction (SCORED) study was designed to evaluate the importance of erection hardness as a patient expectation of pharmacological treatment. A structured questionnaire was used to facilitate diagnosis and discussion of ED and to systematically establish patients' expectations about PDE5i treatment. The profile of ED patients in Belgium was also determined in the study.

## Methods

### *Study design*

SCORED was an observational, multicentre, non-interventional study in Belgian men discussing ED with their GP or urologist. Eligible patients included men over 18 years of age who either consulted a GP or urologist for first diagnosis of ED or were already treated for ED. The protocol was approved by the Ethics Committee of Flemish General Practitioners. All patients provided written informed consent.

### *Data collection*

A structured questionnaire, designed as a logical guide for physicians to run through patient characteristics and stimulate discussion on ED, was used. Patients were asked to provide demographic data and information about the consultation (age, reason for consultation, first time discussion on ED, presence of partner, initiation of ED discussion, steady relationship with partner, spontaneous reference to importance of rigidity of erection, treatment status). The physician and patient were then asked to evaluate the ED using the validated EHS to describe the current state of penile rigidity (before or without treatment).<sup>15,16</sup> Maintenance of erection was evaluated by the question 'How often are you able to maintain your erection until the end of sexual intercourse?', which was based on a question from the validated IIEF.<sup>17</sup> Additional questions

evaluated the duration and causes of ED (aetiology, presence of risk factors, sport activity, physician's request of additional exams, referral to a specialist). Subsequently, oral treatment was discussed (patients' reactions to PDE5i treatment and treatment expectations in terms of penile rigidity, onset of action, maintenance of erection, natural-feeling sexual intercourse and duration of action). Finally, the utility of the questionnaire to facilitate dialogue between physicians and patients on ED and erection hardness was recorded. Data collected using the case report forms were scanned (Lambda-Plus SA) for statistical analysis by an independent expert (Professor A Albert).

### *Statistical methods*

Results were expressed as means  $\pm$  s.d. for quantitative variables and scores, while frequencies and percentages were used for categorical variables. Mean values were compared by one-way analysis of variance or Student's *t*-test, and proportions by  $\chi^2$ -test for contingency tables. Non-parametric Kruskal-Wallis and Wilcoxon's tests were used for comparing samples from different groups when normality assumptions could not be fulfilled. Correlation coefficients (classical or non-parametric Spearman) were calculated for measuring the association between two quantitative variables. Results were considered to be significant at the 5% critical level ( $P < 0.05$ ). Data analysis was carried out using SAS (version 9.1 for Windows) and S-Plus (version 6.2) statistical packages.

## Results

### *Physician characteristics*

A total of 382 physicians participated in this study, of whom 341 (89%) were GPs and 41 (11%) were urologists. Mean ages of the physicians were  $50.0 \pm 8.9$  years and  $45.7 \pm 10.2$  in general and urological practice, respectively. While GPs were evenly distributed among urban, semi-urban and rural areas, urologists practiced mainly in an urban environment.

Additional examinations were considered more often by urologists than by GPs (32 vs 20%). A minority of GPs (14%) encouraged their patients to consult a urologist, and only 4% of physicians advised their patients to see a psychologist or sexologist for their erection problems.

### *Characteristics of patients with ED*

Of 2053 patients screened, 1492 for whom a complete dataset was available were included in the final analysis. Of these, 1338 patients (90%) consulted a GP and 154 (10%) consulted a urologist.

Characteristics of the 1492 patients are summarized in Table 1. Patients had a mean age of  $56 \pm 11$  years and were equally distributed across the Flemish (55%) and French (45%) regions of Belgium. Most patients (89%) were in a stable relationship of more than 1 year.

Of men with ED, 59% had an EHS score of 1 (penis is larger, but not hard) or 2 (penis is hard, but not hard enough for penetration), and only 3.4% were able to achieve an erection score of 4 (Figure 1a). Most patients (83.1%) had trouble maintaining erections until the end of sexual intercourse (Figure 1b). A statistically highly significant correlation between the grade of rigidity and maintenance of erection was found ( $P < 0.0001$ ) (Figure 2). Of patients with a score 4 erection, 68% could maintain the rigidity until the end of sexual intercourse always or most of the time. For score 3 erections, the corresponding percentage was only 25%. Patients practising sport for a mean of  $2.6 \pm 1.7$  h per week showed higher grades of

erection rigidity (odds ratio (OR), 0.75;  $P < 0.05$ ) and less severe ED (OR, 0.71;  $P < 0.05$ ).

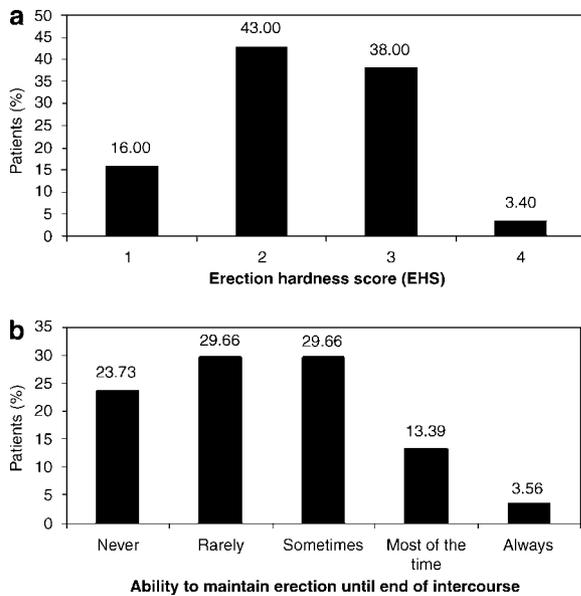
Erectile dysfunction had been discussed with the physician previously by 43% of patients, but 74% of patients were receiving no treatment for ED at the time of the study. Most patients (85%) had at least one known risk factor for ED, and 25% of men reported an ED duration of more than 3 years. The presence of the different risk factors, and the odds that the physician initiated the discussion on ED rather than the patient or partner, are presented in Table 2. Overall, 41% of the patients had three or more risk factors and the number of risk factors increased with age ( $P < 0.0001$ ). Only 18% of physicians initiated the conversation on ED, with GPs more likely to start communication about ED with patients presenting with at least one risk factor, those with diabetes or hypertension, or those receiving medication that could lead to ED (all  $P < 0.05$ ). The presence of depression, hyperlipidaemia or whether a patient smokes did not increase the

**Table 1** Characteristics of the patients presenting with ED

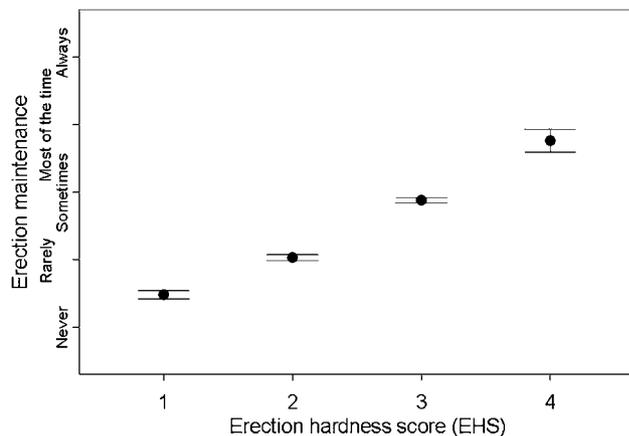
Variable	GP (N = 1338)	Urologist (N = 154)	Total (N = 1492)	P-value
Age (years), mean $\pm$ s.d.	56.6 $\pm$ 10.9	55.3 $\pm$ 11.6	56 $\pm$ 11	0.19
Region (%)				0.70
North	45	47	45	
South	55	53	55	
Stable relationship with partner (%)	89	92	89	0.26
Reason for consultation, n (%)				
ED	553 (41)	110 (72)	663 (45)	<0.0001
Other	764 (57)	39 (25)	803 (54)	
Both	16 (1)	4 (3)	20 (1)	
First discussion of ED (%)	54	78	57	<0.0001
Presence of partner during consultation (%)	20	28	21	0.021
Duration of troubles, n (%)				0.58
< 1 year	441 (34)	56 (37)	497 (34)	
1–3 years	525 (41)	62 (41)	587 (41)	
> 3 years	330 (25)	33 (22)	363 (25)	
Score of erection hardness, n (%)				0.0008
1	203 (15)	34 (22)	237 (16)	
2	593 (45)	43 (28)	636 (43)	
3	491 (37)	68 (44)	559 (38)	
4	42 (3)	8 (5)	50 (3)	
Severity of ED <sup>a</sup> , n (%)				0.36
Mild	173 (13)	26 (17)	199 (14)	
Moderate	642 (50)	68 (46)	710 (49)	
Severe	471 (37)	55 (37)	526 (37)	
Aetiology of ED <sup>a</sup> , n (%)				0.10
Organic	400 (31)	55 (39)	455 (32)	
Psychogenic	350 (27)	29 (20)	379 (27)	
Mixed	526 (41)	58 (41)	584 (41)	
Current ED treatment (%)	26	29	27	0.47

Abbreviations: ED, erectile dysfunction; GP, general practitioner.

<sup>a</sup>According to the physician.



**Figure 1** (a) Erection Hardness Score (EHS) and (b) maintenance of rigidity for patients with erectile dysfunction (ED).



**Figure 2** Association between Erection Hardness Score (EHS) and maintenance of erection until the end of sexual intercourse ( $P < 0.0001$  for all comparisons).

chance of a GP initiating discussion about ED. In urological practice, surgery for prostate cancer increased sevenfold the chance of the physician initiating the discussion ( $P < 0.05$ ).

In urological consultations, partners were significantly more likely to be present than those in general practice. Patients accompanied by their partner were generally older ( $P < 0.05$ ), had more severe ED ( $P < 0.0001$ ) and discussed ED for the first time ( $P < 0.01$ ). When the partner was present, the latter initiated the discussion on ED as often as the patient in general practice (41 vs 42%), while it was primarily the patient in urological practice (17 vs 73%).

### Patient expectations for treatment with a PDE5 inhibitor

Figure 3 presents the initial reaction of patients to discussion of PDE5i treatment. In total, 25% of patients rapidly confirmed their interest, while 34% were already informed about these agents and 21% requested treatment themselves. Concerns about safety were raised only by 7.5% of patients, who were generally older.

The order of preference for patients' expectations of PDE5i treatment is presented in Figure 4. Erection hardness and maintenance of erection were rated as very important by 88.7 and 91.6% of patients, respectively. Natural-feeling sexual intercourse was rated as very important by 63.1% of the patients, while fast onset and long duration of action of treatment were considered to be important by only 30.0 and 16.7% of patients, respectively. When asked to choose between two propositions about their expectations of ED, improvement of erection hardness was clearly preferred over fast onset by 92.4% of patients and over long duration of action by 93.6% of patients. Interestingly, 66 and 71% of the patients in general and urological practice made spontaneous reference to the importance of erection hardness or their wish to obtain a harder erection, especially when ED was the primary reason for consultation ( $P < 0.0001$  for general practice and  $P < 0.05$  for urological practice).

### Utility of questionnaire in discussion of ED and erection hardness

Most GPs (81%) and their patients (83%) considered the questionnaire including the EHS to be a useful tool for initiating communication on ED. In addition, for 87 and 85% of GPs and their patients, respectively, the questionnaire was helpful in prompting discussion of the importance of the penile rigidity. A total of 41% of men who consulted their GP did so because of ED (Table 1).

In urological practice, where 72% of men were consulting for a diagnosis of ED, the questionnaire facilitated the discussion about ED for 68% of the patients but only 46% of urologists. Regarding the discussion of the importance of penile rigidity, 72% of patients considered the questionnaire to be helpful compared with 48% of urologists.

## Discussion

SCORED was designed to characterize patients with ED and to evaluate a questionnaire as a tool for stimulating and facilitating communication on ED and erection hardness. Importantly, satisfaction with erection hardness correlates with sexual satisfaction and improvements in emotional well being, and overall health and quality of life for patients and

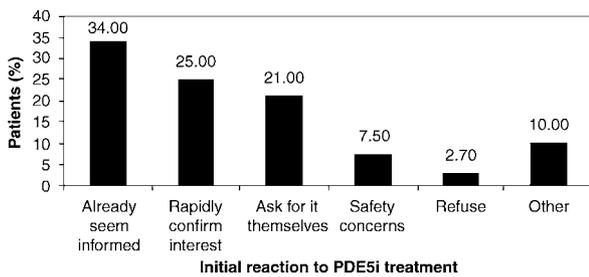
**Table 2** Presence of risk factors and odds for initiating the discussion about ED by the physician, with respect to the presence of risk factors

Variable (vs not present)	Presence of risk factor, N (%)	General practitioner (N = 1338)		Urologist (N = 154)	
		OR	95% CI	OR	95% CI
At least one risk factor		1.64*	1.06–1.54	1.37	0.28–6.59
Additional risk factor		1.18*	1.08–1.28	0.90	0.60–1.34
Diabetes	271 (19)	2.00*	1.45–2.75	1.03	0.21–5.02
Vascular intervention	93 (6.4)	1.15	0.67–1.98		NA <sup>a</sup>
Medication	385 (27)	1.46*	1.09–1.96		NA <sup>a</sup>
Surgery for hyperplasia	65 (4.5)	0.99	0.50–1.93	4.30	0.77–24.1
Surgery for prostate cancer	48 (3.3)	1.23	0.55–2.74	7.00*	1.77–27.8
Hypertension	617 (42)	1.74*	1.32–2.29	1.30	0.39–4.30
Smoking	576 (40)	1.29	0.98–1.29	1.26	0.53–1.88
Hyperlipidaemia	482 (33)	1.00	0.75–1.35		NA <sup>a</sup>
Alcohol	416 (29)	1.09	0.81–1.46	0.44	0.05–3.60
Depression	252 (17)	0.97	0.68–1.38		NA <sup>a</sup>
Angina/chest pains	40 (2.8)	1.29	0.60–2.76		NA <sup>a</sup>

Abbreviations: CI, confidence interval; NA, not available; OR, odds ratio.

<sup>a</sup>The physician never initiated the discussion when the patient presented with this risk factor.

\* $P < 0.05$ .

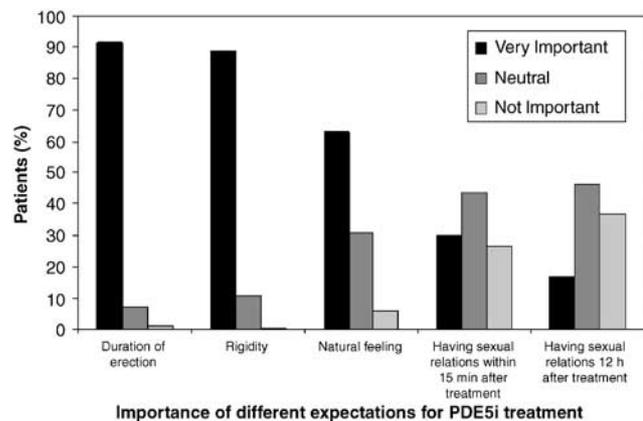


**Figure 3** Initial reaction of the patients to proposition of treatment with a phosphodiesterase type 5 (PDE5) inhibitor.

their partners,<sup>11,14,18–20</sup> and thus evaluation of this parameter is a key part of assessing ED. One way of measuring erection hardness is through use of the EHS,<sup>15,16</sup> and the present study was the first epidemiological study of ED to use this instrument.

Of men included in the analysis, 41% had score 3 or 4 erections, but most men reported an inability to maintain erection until the end of intercourse most of the time. A surprisingly large number of men with score 3 erections (38%) talked about ED with their physician, and maintenance of erection seems to be the reason why most men with score 3 are considered to have moderate instead of mild ED (only 14% of men were considered to have mild ED). Therefore, these patients were actually complaining about maintenance problems due to insufficient rigidity. There is also a significant correlation between rigidity and maintenance of erections, which is to be expected, given the importance of passive venous compression in tumescence phase to provide a good, stable erection.<sup>21</sup>

Duration of ED was <3 years in three-quarters of patients, showing a positive trend compared with a previous study in which only 66% of patients



**Figure 4** Order of preference given by the patients to their expectations of phosphodiesterase type 5 (PDE5) inhibitor treatment.

reported a duration of <3 years.<sup>22</sup> Results of the present study show however that two-thirds of men waited for >1 year before addressing issues of ED with their physician, with the associated detrimental effects on their sexual relationships.<sup>23</sup> Furthermore, most men in the study were in a stable relationship, with the partner present in one-fifth of consultations and often responsible for initiating the discussion on ED. Taken together, these results suggest that there is still some reluctance of men to discuss ED with their physician, and that it is often the partner who seeks counselling. In addition, three-quarters of the patients in the study were not receiving treatment for ED at the time of the study, suggesting that, in contrast to what is often believed, many physicians do not immediately prescribe PDE5i treatment when discussing ED with a patient.

Although ED has been identified as an independent marker of cardiovascular risk, and the majority

of the patients in this study presented with one or more risk factors, physicians initiated communication about ED only in a limited number of cases, and only a minority of physicians requested additional examinations to characterize ED. Moreover, whether a patient smoked, was depressed or had hyperlipidaemia did not increase the chance of a GP initiating discussion about ED. More effort should therefore be made to stimulate physicians to ask men about sexual dysfunction when consulted by patients with one or more co-morbidities. Conversely, screening for other cardiovascular risk factors should be considered when a patient presents with ED.

When the subject of PDE5i treatment was raised, most patients rapidly confirmed their interest, already seemed informed or even requested such treatment themselves. Patients cited rigidity of erections as the most important treatment expectation, while fast onset and long duration of action were considered least important. It was also clear that patients want to talk about erection hardness—66% in general practice and 71% in urological practice made spontaneous reference to the importance of penile rigidity or their wish to obtain harder erections. It appears therefore that patients are less embarrassed as compared to physicians regarding erection hardness during discussions about ED and its treatment. Only a minority of patients worry about safety of PDE5i treatment, and this appears to have decreased substantially from 60% of patients in a previous study<sup>22</sup> to 7.5% in the present study.

Regarding use of a structured questionnaire including EHS, patients and GPs were comfortable with the questionnaire, with most GPs and most of their patients considering it helpful in discussing ED. Moreover, over half of patients discussed ED despite visiting their GP for other reasons. Use of the questionnaire may also facilitate appropriate treatment, as almost three-quarters of patients were receiving no treatment for ED at the time of the study, despite the fact that ED had been discussed with the physician previously by over 40% of patients, and over 40% presented with at least three risk factors for ED. Of patients visiting a urologist, up to 72% considered the questionnaire to be helpful, but less than half of the urologists shared their opinion. These results show that the questionnaire is most useful for GPs, who are less used to discussing ED with their patients as compared to urologists. In addition, urologists see more men because of ED and these men are more likely to initiate a discussion with such a physician, who is more used to hearing about ED. Overall, the results are consistent with a previous study of 1191 physicians, in which a short questionnaire was found to be highly acceptable to patients, prompting 54% of discussions of sexual health.<sup>24</sup>

One important strength of SCORED is the large patient cohort. Furthermore, physicians were not asked to find new patients, but to use the

questionnaire only when they felt it was appropriate to talk about ED or when a patient initiated discussion themselves. Thus, the inclusion criteria for the analysis were very broad. In addition, patients' expectations were discussed and prioritized in four different ways (order of preference; classification according to very important, neutral, not important; binary choice between propositions; spontaneous reference to rigidity by the patient) to avoid biasing answers by the way questions were asked. Notably, there was a high level of consistency between the results of the four approaches. Bias may also have been avoided by the fact that the population consisted mostly of untreated men, reducing expectations based on previous treatment experiences. One possible limitation of the study is that only men who attended a physician (GP or urologist) were included, which could limit extrapolation of the results to the overall male population.

In conclusion, results of the SCORED study show that GPs initiate discussion about ED only in a minority of cases, even when patients have multiple risk factors. In addition, a large number of patients with not fully rigid erections talk about ED with their physician, thus demonstrating the importance of the treatment goal to achieve completely hard erections and, consequently, sufficient maintenance. There is a significant correlation between rigidity and maintenance of erections, and rigidity of erections is also the most important expectation for PDE5i treatment, while fast onset and long duration of action are considered least important. Only a minority of patients worry about safety of PDE5i's. This should encourage the physician to avoid hesitating when initiating treatment, even at the first consultation. Overall, the results show that a questionnaire including EHS is useful to facilitate discussion about ED in general practice.

## Acknowledgments

The study was funded by Pfizer, Belgium. Editorial support was funded by Pfizer International Operations, Paris. Professor Claes received consulting fees from Pfizer, Bayer and Lilly ICOS; Professor Opsomer received consulting fees and a research grant from Pfizer, Bayer and Lilly ICOS; Dr Andrienne received consulting fees and a research grant from Pfizer; Professor Albert received consulting fees from Pfizer, Bayer and Lilly ICOS. Mr Vanderdonck is employed by Pfizer.

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