The effect of advertising in clinical software on general practitioners' prescribing behaviour

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ABSTRACT

Objective: To assess the effect of pharmaceutical advertising embedded in clinical software on the prescribing behaviour of general practitioners.

Design, participants and setting: Secondary analysis of data from a random sample of 1336 Australian GPs who participated in Bettering the Evaluation and Care of Health, a national continuous cross-sectional survey of general practice activity, between November 2003 and March 2005. The prescribing behaviour of participants who used the advertising software was compared with that of participants who did not, for seven pharmaceutical products advertised continually throughout the study period.

Main outcome measures: Prescription for advertised product as a proportion (%) of prescriptions for all pharmaceutical products in the same generic class or group.

Results: GP age, practice location, accreditation status, patient bulk-billing status and hours worked were significantly associated ($P < 0.05$) with use of advertising software. We found no significant differences, either before or after adjustment for these confounders, in the prescribing rate of Lipitor (adjusted odds ratio [AOR], 0.90; $P = 0.26$); Micardis (AOR, 0.98; $P = 0.91$); Mobic (AOR, 1.02; $P = 0.89$); Norvasc (AOR, 1.02; $P = 0.91$); Natrilix (AOR, 0.80; $P = 0.32$); or Zanidip (AOR, 0.88; $P = 0.47$). GPs using advertising software prescribed Nexium significantly less often than those not using advertising software (AOR, 0.78; $P = 0.02$). When all advertised products were combined and compared with products that were not advertised, no difference in the overall prescribing behaviour was demonstrated (AOR, 0.96; $P = 0.42$).

Conclusion: Exposure to advertisements in clinical software has little influence on the prescribing behaviour of GPs.

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Over recent decades, a number of factors have been shown to influence the prescribing behaviour of general practitioners. These include guideline reminders and educational interventions,[1-3] scientific journal articles,[4] detailing visits from pharmaceutical company representatives (which may include promotional materials and product samples),[5-7] attitudes of peers and "opinion leaders" or authority figures,[8,9] prescribing behaviour of specialists or hospital physicians,[10,11] patient expectation,[12-14] advertising in medical journals and periodicals,[11,15-17] and industry sponsorship of education and gifts ranging from meals to conference travel expenses to research funding.[5,18,19] While a great deal of literature describes the effects of advertising and other methods of promotion,[20-22] doctors generally feel that they are immune to the effects of these influences.[4,5,8,21]

Interested stakeholders are keen to know what "works best" either to use that method of promotion, or to curtail it where possible, depending on their perspective. Such stakeholders include: general practice educational bodies advocating best practice, and those promoting Quality Use of Medicines (QUM); government groups interested in judicious prescribing both for QUM and for reasons of economy; and the pharmaceutical industry looking to maximise profits.

In the early 1990s, the first (and currently, only) clinical software system with embedded advertising (referred to hereafter as "the advertising software") was released to medical practitioners in Australia. The vendors used an advertising revenue strategy to offset the cost of the product, and sent a full working copy to all GPs.[23] During the period of this study (1 November 2003 to 28 March 2005), the types of advertisements embedded in the software included full-screen images and "strip messages", with or without animation. The "pop-up" full-screen advertisements appeared when any document was printed (this function has since been removed). The strip messages cycled through the program's screens during the course of each work session, at the opening of each patient record, when new data were added to a record, and when prescriptions or pathology test orders were prepared. The strip advertisements were also displayed when the software's clinical support tools were accessed. The software developers provided quarterly updates, and advertisements could change with each new version. The advertisements cycled for a month within each version, allowing for three different sets of advertisements to be shown within the quarter. An advertisement could be repeated in all three sets, and in multiple cycles.

At the commencement of this study, the price of primary full-screen advertisements was $7380 for 1 month ($19 557 for 3 months) and for the minor strip advertisements was $4768 for 1 month ($12 675 for 3 months).[24] While most advertisements were for pharmaceutical products, advertising "space" had also been purchased by medical indemnity insurers, private health insurers, pathology services, Divisions of General Practice, employment networks, the Australian Government Department of Health and Ageing (DoHA), and other non-profit organisations such as the National Heart Foundation Australia, the National Prescribing Service, and Médecins sans Frontières.

A 2005 review of the advertising software[25] reported that 95% of pharmaceutical advertisements appeared to be non-compliant with the Medicines Australia Code of Conduct[26] through one or more of the following: missing information; illegibility of generic names; claims that were unsubstantiated; lack of Pharmaceutical Benefits Scheme (PBS) listing information; or were in breach of the *Therapeutic Goods Act 1989* (Cwlth) regarding direct-to-consumer advertising of pharmaceutical products.[25]

The aim of our study was to examine the effect of advertisements embedded in clinical software on the prescribing behaviour of the GPs who use it.

METHODS

Our data were drawn from the national Bettering the Evaluation and Care of Health (BEACH) program. The BEACH methods

1 General practitioner and practice variables tested for their association with use of advertising software for clinical purposes

General practitioner characteristics	Practice characteristics
• Age (< 45, 45–54, 55 + years)*	• Size of practice (solo, 2–4, 5–10,11 + GPs)*
• Sex*	• Practice location by Rural, remote and metropolitan areas classification[29] (metropolitan/rural)
• Place of graduation (Australia/other)*	• Practice location by Australian standard geographical classification[30] (major city/not major city)*
• Fellow of the Royal Australian College of General Practitioners (yes/no)*	• Socioeconomic status by Socio-economic indexes for areas (SEIFA) classification (Disadvantaged, SEIFA < 4; less disadvantaged, SEIFA 4–11)[31]
• Years in general practice (< 10, 10–19, 20 +)†	• Practice accreditation status (yes/no)*
• Years since graduation (< 20, 20–29, 30 +)†	• Practice nurse at major practice address (yes/no)*
• Sessions per week (< 6, 6–10, 11 +)	• After-hours patient-care arrangements (own or cooperative/deputising service)
• Direct patient-care hours per week (< 31, 31–40, 41–50, 51 +)*	
• Work in past 4 weeks: ➢ in residential aged-care facility (yes/no) ➢ as a locum (yes/no) ➢ as salaried/session hospital medical officer (yes/no)* ➢ in a deputising service (yes/no)	
• Bulk bill all patients (yes/no)*	
• Any consultations in language other than English (yes/no)	
• Registered with Department of Veterans' Affairs (yes/no)	
• Registrar status (registrar/not registrar)	

* Variables that showed some association ($P < 0.10$) with use of advertising software for clinical purposes, and were therefore included in the logistic regression analysis. † Variables that were found to be highly correlated with other variables and were therefore eliminated from the logistic regression analysis. ◆

have been published in detail elsewhere,[27] but relevant features are summarised here. BEACH is a paper-based, continuous cross-sectional survey of general practice activity. Each year about 1000 GPs from a national rolling random sample (drawn by the DoHA) participate in BEACH. The sample used in our analysis was representative of the GP population in Australia.[27] GPs provide demographic and encounter information for 100 consecutive, consenting, unidentified patients. They also provide demographic information about themselves and their practices on a GP-profile questionnaire. The foci for this study were questions related to the GPs' individual computer use for clinical purposes. Each GP was asked: "To what extent are computers used by you at work?", with numbered response options of: "not at all"; "test ordering"; "prescribing"; "medical records"; "Internet"; and "email". They were also asked what prescribing and medical record software they used. For this analysis, prescriptions recorded by GPs, and the software program they use for clinical purposes were the elements investigated for 1336 GPs participating in BEACH between 1 November 2003 and 28 March 2005. Medications prescribed were coded at the product level according to an in-house system known as CAPS, and were classified at the generic level according to the Anatomical Therapeutic Chemical (ATC) classification.[28]

GPs were assigned to one of two groups: those exposed to advertising (users of the advertising software for prescribing and/or test ordering and/or medical records, with or without email and/or Internet); and those not exposed to advertising (GPs who used other software, did not use a computer for clinical purposes or did not use a computer at all).

Although the date of encounter is one of the elements collected in BEACH, and we had a release date for each software update, we could not be certain that updates had been installed immediately when received and so were unable to reliably align dates of encounter with advertisements supposedly being shown on those dates. However, there were seven pharmaceutical products that had been advertised continuously throughout each month and in each version of the advertising software for the duration of the study period: Lipitor (atorvastatin [Pfizer Australia, Sydney, NSW]); Micardis (telmisartan [Boehringer Ingelheim, Sydney, NSW]); Mobic (meloxicam [Boehringer Ingelheim, Sydney, NSW]); Nexium (esomeprazole [AstraZeneca, Sydney, NSW]); Norvasc (amlodipine besylate [Pfizer Australia, Sydney, NSW]); Natrilix (indapamide hemihydrate [Servier Laboratories (Aust), Melbourne, Vic); and Zanidip (lercanidipine hydrochloride [Solvay Pharmaceuticals, Sydney, NSW]). Nexium had been on the market for 13 months, and all other brands for a minimum of 18 months before the study's commencement.

Statistical analysis

The sample of GPs was a simple random sample, so we used conventional simple random sample methods for GP-based comparisons. The sample of encounters was a cluster-based sample, so we adjusted the 95% confidence intervals and *P* values reported for the single-stage clustered study design using procedures in SAS, version 8.2 (SAS Institute, Cary, NC, USA). A-priori power estimations for two-sample comparison of proportions were performed with Stata, version 8.0 (StataCorp, College Station, Tex, USA).

We made univariate comparisons of the characteristics (listed in Box 1) of the GPs in each group, eliminated those highly correlated with others, and used simple logistic regression to identify those associated ($P < 0.10$) with use of advertising software for clinical purposes. We used stepwise procedures[32] in logistic regression analysis to identify characteristics independently related to advertising software use for clinical purposes ($P < 0.05$). The prescribing outcomes were categorised as advertised brand or non-advertised products. Logistic regression was used to analyse the categorical outcomes, after adjusting for the potential confounding variables. Results are expressed in terms of odds ratios with unexposed GPs as the reference group (odds ratio [OR], 1). Prescriptions for each of the seven advertised products as a proportion of prescriptions for all products in the same ATC class were compared between the GP groups (eg, the proportion of HMG CoA [3-hydroxy-3-methylglutaryl coenzyme-A] reductase inhibitor prescriptions that were for Lipitor). In a few cases, a product under investigation and another product from the same ATC class or group had been prescribed for the same problem at the encounter. These cases were removed from the analysis as they were no longer mutually exclusive.

2 Variables independently associated with general practitioner use of advertising software for clinical purposes and included in the final model

General practitioner or practice variables	General practitioners exposed to advertising software		Logistic regression odds ratio			
	Yes	No	Unadjusted (univariate) (95% CI)	*P*	Adjusted (multivariate) (95% CI)	*P*
Age of GPs						
< 45 years	287 (37.1%)	125 (27.8%)	1	< 0.001	1	< 0.001
45–54 years	262 (33.9%)	135 (30.1%)	0.85 (0.63–1.14)		0.87 (0.64–1.19)	
55 + years	224 (29.0%)	189 (42.1%)	0.52 (0.39–0.69)		0.56 (0.41–0.77)	
Bulk-billing status						
Does bulk bill all patients	168 (21.8%)	166 (37.0%)	1	< 0.001	1	< 0.001
Does not bulk bill all patients	601 (78.2%)	283 (63.0%)	2.10 (1.62–2.71)		1.68 (1.27–2.22)	
Practice location*						
Major city	486 (63.0%)	331 (73.7%)	1	< 0.001	1	0.02
Not major city	285 (37.0%)	118 (26.3%)	1.64 (1.27–2.12)		1.38 (1.05–1.83)	
Practice accreditation status						
Yes	677 (88.0%)	321 (72.1%)	1	< 0.001	1	< 0.001
No	92 (12.0%)	124 (27.9%)	0.35 (0.26–0.48)		0.43 (0.31–0.60)	
Direct patient care hours/week						
0–30 hours	192 (25.4%)	108 (24.8%)	1	0.09	1	0.03
31–40 hours	226 (29.9%)	159 (36.6%)	0.80 (0.59–1.09)		0.83 (0.60–1.15)	
41–50 hours	221 (29.2%)	114 (26.2%)	1.09 (0.79–1.51)		1.23 (0.87–1.74)	
51+ hours	117 (15.5%)	54 (12.4%)	1.22 (0.82–1.82)		1.39 (0.91–2.12)	

* By Australian standard geographical classification.[30]

Where two strengths of the same product were prescribed (eg, Lipitor 20 mg and Lipitor 40 mg), these were counted as a single prescription for the product. The final step was to determine if combining the data from the seven comparisons would detect a different overall effect. We grouped the seven brands together and the total number of prescribing decisions for advertised medications were compared as a proportion of all prescribing decisions in the combined ATC classes.

Ethical approval

BEACH and additional data collection for this study was approved by the Human Research Ethics Committee of the University of Sydney and the Ethics Committee of the Australian Institute of Health and Welfare.

RESULTS

Of the 1336 GPs who participated during the study period, 79 did not provide responses about their use of computers, and 35 did not report which software they had; these were excluded from the analyses. Of the 1222 remaining GPs, 773 (63.3%) reported using the advertising software and provided information about 77 300 encounters involving 63 335 prescribed medications. The 449 (36.7%) who did not use the advertising software provided information about 44 900 encounters involving 37 895 prescribed medications. The GP and practice characteristics were tested for association with use of advertising software, and those included in the final model are shown in Box 1. Five GP characteristics — GP age, patient bulk-billing status, practice location, practice accreditation status and weekly hours worked in direct patient care — were found to be independently associated ($P < 0.05$) with GP use of the advertising software. GPs who were using the advertising software were significantly more likely to be aged less than 45 years ($P < 0.001$), to live in areas other than major cities ($P = 0.02$), and to work in accredited practices ($P < 0.001$), and significantly less likely to bulk bill all their patients ($P < 0.001$) and to work 31–40 hours per week in direct patient care ($P = 0.03$) (Box 2).

In the prescribing data, there were 29 prescriptions removed in which both the advertised and a non-advertised product were prescribed for the same problem. These are enumerated for each ATC class in the footnote to Box 3.

We found no significant differences between the two GP groups, either before or after adjustment, in the prescribing rate of Lipitor (adjusted odds ratio [AOR], 0.90; $P = 0.26$); Micardis (AOR, 0.98; $P = 0.91$); Mobic (AOR, 1.02; $P = 0.89$); Norvasc (AOR, 1.02; $P = 0.91$); Natrilix (AOR, 0.80; $P = 0.32$); or Zanidip (AOR, 0.88; $P = 0.47$). For Nexium, a significant difference emerged after adjustment between the two groups (AOR, 0.78; $P = 0.02$) — the GPs who were exposed to the advertising software prescribed this product less often than those not exposed. When the seven products were combined, there was no difference in the overall prescribing behaviour between the two groups either before or after adjustment (AOR, 0.96; $P = 0.42$) (Box 3).

DISCUSSION

We found that exposure to advertisements embedded in clinical software had one significant and selective effect on the prescribing behaviour of the GPs in this study.

3 Distribution of prescriptions: advertised medication brands versus other brands within the same Anatomical Therapeutic Chemical (ATC) drug groups[28]

Problems managed with at least one prescription for:	Prescriptions by general practitioners exposed to advertising software		Logistic regression odds ratio			
	Exposed	Not exposed	Unadjusted (univariate) (95% CI)	*P*	Adjusted (multivariate)* (95% CI)	*P*
3-hydroxy-3-methylglutaryl coenzyme-A reductase inhibitors (ATC code: C10AA)†	2162	1348	0.91 (0.76–1.07)	0.26	0.90 (0.76–1.08)	0.26
Lipitor	983 (45.5%)	646 (47.9%)				
Other	1179 (54.5%)	702 (52.1%)				
Agents acting on the renin–angiotensin system (ATC code: C09)‡	3927	2576	0.88 (0.62–1.25)	0.48	0.98 (0.66–1.45)	0.91
Micardis	169 (4.3%)	125 (4.9%)				
Other	3758 (95.7%)	2451 (95.1%)				
Anti-inflammatory and antirheumatic products, non-steroids (ATC code: M01A)§	3107	2039	1.02 (0.80–1.30)	0.89	1.02 (0.78–1.33)	0.89
Mobic	458 (14.7%)	296 (14.5%)				
Other	2649 (85.3%)	1743 (85.5%)				
Proton pump inhibitors and H_2-receptor antagonists (ATC codes: A02BC, A02BA)¶	1955	1170	0.84 (0.69–1.03)	0.10	0.78 (0.63–0.96)	0.02
Nexium	487 (24.9%)	330 (28.2%)				
Other	1468 (75.1%)	840 (71.8%)				
Calcium channel blockers (ATC code: C08)**	1491	914	1.03 (0.85–1.25)	0.76	1.02 (0.82–1.25)	0.91
Norvasc	465 (31.2%)	279 (30.5%)				
Other	1026 (68.8%)	635 (69.5%)				
Total low-ceiling diuretics (ATC codes: C03A, C03B)††	424	232	0.81 (0.54–1.21)	0.30	0.80 (0.51–1.25)	0.32
Natrilix	257 (60.6%)	152 (65.5%)				
Other	167 (39.4%)	80 (34.5%)				
Calcium channel blockers (ATC code: C08)‡‡	1492	912	0.85 (0.62–1.16)	0.30	0.88 (0.62–1.25)	0.47
Zanidip	148 (9.9%)	105 (11.5%)				
Other	1344 (90.1%)	807 (88.5%)				
All medication decisions included above	14 558	9191	0.96 (0.88–1.05)	0.38	0.96 (0.87–1.06)	0.42
Advertised brand medications	2967 (20.4%)	1933 (21.0%)				
Non-advertised brand medications	11 591 (79.6%)	7258 (79.0%)				

*Model controlling for the following GP/practice characteristics: age, practice location, bulk-billing all patients status, practice accreditation status, hours per week worked in direct patient care. † 1 encounter excluded because of coprescription of Lipitor (Pfizer Australia, Sydney, NSW) and another brand within this group. ‡ 15 encounters excluded because of coprescription of Micardis (Boehringer Ingelheim, Sydney, NSW) and another brand within this group. § 4 encounters excluded because of coprescription of Mobic (Boehringer Ingelheim, Sydney, NSW) and another brand within this group. ¶ 5 encounters excluded because of coprescription of Nexium (AstraZeneca, Sydney, NSW) and another brand within this group. ** 1 encounter excluded because of coprescription of Norvasc (Pfizer Australia, Sydney, NSW) and another brand within this group. †† No encounters excluded because of coprescription of Natrilix (Servier Laboratories (Aust), Melbourne, Vic) and another brand within this group. ‡‡ 3 encounters excluded because of coprescription of Zanidip (Solvay Pharmaceuticals, Sydney, NSW) and another brand within this group. ◆

However, this effect was subsumed in the overall result when all seven products were grouped.

As with all observational studies, the influence of confounding factors requires consideration. We do not know, for instance, the exposure to advertising at the exact time of prescribing. We could not determine what exposure GPs had to advertising through other media, but assumed that GPs in both groups had an equal chance of exposure to advertisements through such avenues as scientific journals, periodicals, and visits from pharmaceutical representatives. We did not investigate the appropriateness of the chosen medication for the condition for which it was prescribed — our purpose was to detect any influence of the

advertising once the decision to prescribe had been made. We also had no way of examining the effect, if any, on patients exposed to the advertisements, and acknowledge that patient request is a recognised influence on how GPs prescribe.[12-14] It would have been interesting to compare brand choice for those medications being prescribed for the patient for the first time, rather than all medications, as a new choice must be made at that point. However, new prescriptions form a very small proportion of all prescriptions, particularly in the area of chronic disease management, so this would have resulted in too small a sample size for meaningful comparison.

For all but one sample (low-ceiling diuretics), the sample size was sufficient to detect a difference of 5% with power at 0.81 or over. Because the differences between the groups were so small (ranging from 0.2% to 4.9%), there may be insufficient power in some of the sample sizes to conclude the null effects with certainty (ie, type II errors might have been incurred). However, the sample size for proton-pump inhibitors/H_2-receptor antagonists (3125 cases) has power calculated at 0.85, giving greater reliability to the Nexium result. We had hypothesised that the promotion would produce greater prescribing of the advertised product, and we think it is clinically significant that the result is the opposite of that hypothesised. If we have reported a difference where in fact none exists (ie, a type I error), this further supports a finding of no difference, and that the influence of advertising through clinical software was not proven.

Although this is the first study to examine the effect of advertising in clinical software, other studies have had similar results when examining the relationship between prescribing and advertising in journals. One found no relationship between the extent of advertising for a drug and the amount of prescribing by GPs.[11] Another reported no correlation between changes in expenditure on detailing visits from pharmaceutical company representatives or on journal advertising and size of market or market share.[33] It concluded that the most likely cause of its negative results was that there is so much spent on promotion that additional advertising makes little difference to prescribing under the law of diminishing returns.[33] As most promotional funds are spent on detailing visits by representatives, and a comparative paucity on media advertising,[34] there may be so much compared with so little that the extra amount spent on advertising in software makes no difference.

Incidental exposure of patients to advertisements is one aspect of the ethical debate about advertisement-embedded software, but exposure of GPs is the dominant one, and has echoes of the same issues involved in pharmaceutical advertising in medical or scientific journals.[11,15-17] The assumption that this method of advertising influences prescribing behaviour is supported by the amount of advertising commissioned by pharmaceutical companies. One report used the example of advertisements in the *New England Journal of Medicine* and the *Journal of the American Medical Association*, which produce multiple versions of the same journal that have the same text but different pharmaceutical advertisements, depending on the geographical region and physician specialty intended for that version. Primary care physicians receive editions with the most advertisements, and libraries receive those with the fewest.[16] This collaboration in promoting pharmaceutical products does not correlate with best practice ideals and creates a potential conflict of interest for the organisations publishing the journals and for their policies. Nonetheless, this advertising offsets the production cost of the journals and is a significant source of funding for some physician organisations that, in some cases, might not exist without it.[16]

To some extent, the same dilemma is assumed for users of advertising software — removing the advertisements would mean removing the subsidy made available through advertising revenue, and the software would then become more expensive for its purchasers. Despite the obvious amount of revenue contributed by advertisements, and acknowledging that there is similar software available at a much higher price, the current price of the advertising software aligns with at least two similar clinical software packages presently available in Australia, which do not have advertisements.

There are a couple of other considerations in the ethical debate where advertisement-embedded software is concerned. It could be argued that provision 3.10.11 (of edition 14, now 3.9.2 of edition 15) of Medicines Australia's Code of Conduct[26,35] is being breached when advertisements are clearly aimed at a condition or clinical function with which the condition is associated (eg, the only two advertisements in the cardiovascular monitor tool were for Micardis or Norvasc; the only two in the product information tool for musculoskeletal drugs were for Celebrex and Mobic). Edition 15 (provision 3.9.1) of the Code now precludes a company from placing advertisements with clinical tools.[35] The pharmaceutical industry is held responsible for any breaches. But with effective industry standards and accreditation for clinical software, these regulations might be better followed and breaches better controlled.

In our study, the advertisements for Nexium had a negative effect on the GPs exposed to them. Some GPs providing feedback in a previous study stated that the advertisements were "annoying",[25] and our result may be associated with an "annoyance" factor — the strip advertisement for Nexium appeared in the pathology ordering tool continually throughout the study period, as well as in the routine display through the software's general cycle of advertisements. While warnings and reminders can be switched off in the software, the advertisements are very difficult for the average user to eliminate. In any case, the software has achieved market dominance, so neither moral indignation nor the annoyance factor appear to have the same influence as the perceived cost saving. Computerisation is an expensive process, requiring continuing updates of hardware, software and other associated equipment. It has become almost essential, and the costs are borne by the practice. Given that the advertising software no longer has a cost advantage, practices may begin to reconsider their choice of software. However, the advertising software has "first-to-market" advantage, and "vendor lock-in" arising from a lack of standards to facilitate data transfer between systems may deter many from considering change.

While we could measure differences in the prescribing behaviour for the products nominated, we could not test the effect of advertisements for the not-for-profit organisations. Given the cost of these advertisements, and that this mode of advertising may not effect an increase in prescriptions for the advertised product, this may not be the best use of advertising expenditure. The pharmaceutical industry may be able to absorb the cost of this questionably efficient method of promotion (and one that also exposes it to criticism and potential fines for breaches of the Medicines Australia Code of Conduct) on the basis of possible marginal increases in sales (within the confidence intervals shown in this study), but organisa-

tions being funded by the public purse may not be as able to justify such expenditure.

Our study suggests that advertisements in clinical software may have no impact on prescribing, or may even reduce prescribing, but it does not exclude the possibility that such advertisements increase prescribing marginally but sufficiently to provide a competitive return on investment. In light of our results, we invite both the pharmaceutical industry and government organisations to publish their own evaluation data that may contradict our findings.

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COMPETING INTERESTS

None identified.

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