Benefits and harms of direct to consumer advertising: a systematic review

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Background: Direct to consumer advertising is increasingly used by the pharmaceutical industry, but its benefits and harms have yet to be summarised in a comprehensive and rigorous manner.

Methods: A systematic review was conducted of robust evaluations of the impact (positive and negative) of direct to consumer advertising. A broad range of databases and data sources (including Cinahl, Embase, HMIC, HSRProj, Medline, Psychnfo, and the internet) were searched from inception to 2004.

Results: From 2853 citations only four reports were found that met the strict inclusion criteria and provided usable results. Direct to consumer advertising is associated with increased prescription of advertised products and there is substantial impact on patients’ request for specific drugs and physicians’ confidence in prescribing. No additional benefits in terms of health outcomes were demonstrated.

Discussion: Direct to consumer advertising is banned in most countries, and the research evidence tends to support the negative impact that is feared by those who support a legislative ban. Further research is needed into the clinical and economic impact of direct to consumer advertising in healthcare systems.

There is a clear division between those who would support DTCA and those who oppose it. Ongoing debates relating to the role of DTCA, and whether legislation should remain or be changed, have hitherto been made on the basis of selective reporting of research evidence. To our knowledge, there has not been an attempt to produce a systematic overview of the research evidence into this topic. Systematic reviews have the potential to inform both patient care and health policy. In order to inform the debate on DTCA, we have conducted a systematic review of the clinical and economic impact of DTCA on patients and clinicians—both positive and negative.

METHODS

We carried out our systematic review according to clear guidelines set down by the UK NHS Centre for Reviews, and our results are presented according to guidelines laid down in the QUOROM statement.

Search strategy

We searched a wide range of biomedical, psychological, “grey” literature, and marketing databases (ABI Global, Cinahl, Embase, HMIC, HSRProj, Medline, Psychnfo, Sigle, Web of Science, Medline Plus and PreMedline, DARE, and NHS Economic Evaluation Database) from 1987 to October 2004. Free text search terms were created around the term “direct to consumer advertising” and associated synonyms. Medical subject headings (MeSHs) relating to consumer attitudes, patient education, consumer health information, drug information, advertising, and marketing were also explored. The reference lists of included studies were scrutinised for further studies and keyword searches of the internet were also undertaken.

Study inclusion criteria

Studies were included that examined the impact of any form of mass media DTCA of prescription only medicines on the following outcomes:

Abbreviations: DTCA, direct to consumer advertising
• health seeking behaviours of patients at the point of access
to care;
• requests for prescription only medicines;
• patient-doctor communication and satisfaction with care;
• prescribing patterns;
• direct and indirect costs (including drug costs, healthcare
and social costs).

Studies that only reported knowledge and awareness of
advertising campaigns were excluded.

Mass media and population level interventions such as
DTCA are rarely evaluated using randomised designs.
However, in order to draw causal inference from studies
examining population level interventions, it is important to
use control groups or comparative historical time periods.1
For this reason, we decided to extend our inclusion criteria
beyond the conventional randomised controlled trial. In line
with guidelines suggested by the Cochrane Effective Practice
and Organisation of Care (EPOC) group,6 the following study
designs were included: randomised controlled trials, con-
trolled clinical trials, controlled before-and-after studies, and
interrupted time series analyses. We also included cross-
sectional surveys where they included a control or compar-
ison group. We sought full economic evaluations based on
the above epidemiological designs, combining cost and
consequence.11

Study selection
The results of our literature searches were scrutinised
independently by two researchers. References to studies
which could potentially be included were ordered and
scrutinised further. A flow diagram describing the inclusion
and rejection of studies is shown in fig 1.

Data extraction, quality assessment, and research
synthesis
Data were independently extracted by two researchers. Data
on study design, population, intervention, outcomes, results,
and method of analysis were initially summarised in a
tabular form. Study quality was assessed according to
accepted criteria.7

We anticipated that substantial heterogeneity in terms of
study design, populations, and mode of DTCA might be
found among the studies, making a formal statistical method
of synthesis (meta-analysis) inappropriate. We therefore
conducted a descriptive synthesis in line with accepted
guidelines.7 Salient design features and outcomes were
considered, with due reference to the overall quality of the
evaluation. For example, prospective controlled studies were
considered superior to cross sectional studies, and inter-
rupted time series were considered to be interpretable when
several time points before and after the intervention or
introduction of DTCA were presented.

RESULTS
Our searches identified 2853 publications from which only
four studies (six publications) met our strict inclusion criteria
and provided usable data (table 1). Very few of the reports
identified by our searches did, in fact, represent actual
evaluations of the impact of DTCA. Of the studies that did not
fulfil our strict inclusion criteria, many were reports of the
impact of DTCA in increasing brand awareness in the form of
population surveys and opinion polls—for example, the
national survey of consumer reactions to direct to consumer
advertising10—these were not included as they were neither
controlled nor did they examine actual behaviour or our
specified healthcare outcomes. Of the studies that did directly
examine the impact of DTCA in relation to health care,
common reasons for exclusion were: the failure to use a
control group in cross sectional studies13 or descriptions of
spending on DTCA without reference to a specific drug or
product or clinical context.14 Of the economic studies that
were identified, none combined cost and consequence within
the context of a robust epidemiological design, but either
described drug costs alone or relied on economic modelling
and econometric prediction.15

Of the four included studies, three were interrupted time
series, comparing periods of time before and after the
introduction of DTCA.16–17 Two interrupted time series studies
conducted in the US found a significantly increased trend in
the prescribing volume of drugs that had been the subject
of DTCA campaigns.16,17 The effect of DTCA seemed to both
increase the number of new diagnoses of a condition and
tended to increase the proportion of prescriptions specifically
for the advertised drug. For example, Zachy et al17 found that
advertising budgets for cholesterol lowering drugs increased
year on year during the 1990s, and that every $1000 spent
advertising cholesterol lowering drugs was associated with
approximately 32 extra people being diagnosed with hyper-
lipidaemia and 41 advertised cholesterol lowering drugs
being prescribed. Similarly, Basara16 found that a specific
campaign for a migraine treatment (sumatriptan) was
associated with a marked increase in sales over the first
month of a campaign (p<0.0006) which, if extrapolated
across the US market, was associated with $11.5 million in
sales annually.

A European study18 examined the impact of a mass media
campaign sponsored by a pharmaceutical company to
increase awareness of and treatment for a fungal nail
condition (onchomycosis). A ban on product specific DTCA
prevented the company naming their product, but the overall
“awareness campaign” was associated with both an increase
in new prescriptions and the market share of the company’s
specific antifungal agent (increased prescribing volume
during the period of the campaign from 6.50 prescriptions
per 1000 person years (95% CI 6.33 to 6.66) to 15.2 (95% CI
13.5 to 16.9)).

A controlled study by Mintzes and colleagues19–21 examined
the impact of DTCA in the US compared with Canada (where
DTCA is banned, although cross border exposure to DTCA
still exists) using a cross sectional survey of physicians and
patients. Patients in the US were more likely to request DTCA
drugs (7.3% v 3.9%, OR 2.2, 95% CI 1.2 to 4.1), and physicians
in both settings were more likely to acquiesce to these

Figure 1 QUOROM study flow diagram.6
Table 1 Comparative studies examining the impact of direct to consumer advertising which fulfilled inclusion criteria

<table>
<thead>
<tr>
<th>Study and design</th>
<th>Population/setting</th>
<th>Intervention</th>
<th>Outcomes studied and follow up</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basara et al</td>
<td>US primary care</td>
<td>DTCA initiated after 1993 “Brand name” product specific print or television DTCA. Targeted at “common conditions” (excluding “cosmetic or lifestyle” drugs)</td>
<td>New prescription volume (monthly aggregates) of drugs subject to DTCA. Derived from “physician level” prescribing data</td>
<td>DTCA resulted in increased prescribing volume (F&lt;0.05, p&lt;0.00001). The sustained increase in prescription volume was subject to exponential decline as the marketing campaign progressed. Sales response decreased exponentially following termination of DTCA</td>
<td>Clustering of physician and demographic characteristics accounted for in design and analysis</td>
</tr>
<tr>
<td>Mintzes et al</td>
<td>Four representative geographical areas in the US</td>
<td>Migraine treatment (sumatriptan) chosen as an exemplar</td>
<td>Six months data pre DTCA and 11 months post DTCA analysed</td>
<td>Patients believed that they needed medication more often in Sacramento than in Vancouver (OR 2.6, 95%CI 1.3 to 4.3). Specific belief that this should be a DTCA drug also higher (OR 1.4, 95% CI 1.1 to 1.8). Most common request for branded antihistamines</td>
<td>Clustering and demographics accounted for in design and analysis</td>
</tr>
<tr>
<td>Mintzes et al</td>
<td>Primary care</td>
<td>DTCA of any type used in US (1999–2000)</td>
<td>Patients’ requests for medications</td>
<td>Patients requested specific DTCA drugs more often in Sacramento than in Vancouver (7.3% vs 3.2%, OR 2.2, 95% CI 1.2 to 4.1) Patients were more likely to receive a prescription of a DTCA drug than a non-DTCA drug (OR 8.7, 95% CI 5.4 to 14.2); rate similar in Sacramento and Vancouver. Those who requested a specific DTCA drug were more likely to receive a new prescription (for any drug) than those who did not (OR 16.9, 95% CI 7.5 to 38.2)</td>
<td>Clinicians more likely to express dissatisfaction or ambivalence with patient requested drugs (OR 16.9, 95% CI 7.5 to 38.2)</td>
</tr>
<tr>
<td>Mintzes et al</td>
<td>Netherlands primary care</td>
<td>DTCA mass media campaign on onychomycosis (fungal nail infection) by Novartis, a manufacturer of terbinafine</td>
<td>Prescription volume of terbinafine (product of the company initiating the awareness campaign)</td>
<td>Prescription volume for terbinafine increased during the period of the campaign from 6.50 prescriptions per 1000 person years (95% CI 6.33 to 6.66) to 15.2 (95% CI 13.5 to 16.9)</td>
<td>Scant methodological details making it difficult to comment on method of analysis. However, several data points available before and during the campaign</td>
</tr>
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<td>Mintzes et al</td>
<td>Research database containing prescribing information on 150 practices (470775 patients, 1.5 million patient years) between 1996 and 2002</td>
<td>Advertising campaign between 2000–2001</td>
<td>Prescription volume of itraconazole (generic drug also available for treating onychomycosis)</td>
<td>Prescription volume of itraconazole fell from 6.84 prescriptions per 1000 person years (95% CI 6.67 to 7.01) to 6.07 (95% CI 5.86 to 6.28)</td>
<td>New consultation rate for onychomycosis</td>
</tr>
<tr>
<td>Mintzes et al</td>
<td>Research database containing details of 195577 clinicians; DTCA campaigns from 1992 to 1997 correlated with an advertising database detailing all advertising expenditure for named drugs subject to direct to consumer advertising (including TV, radio, print media)</td>
<td>Advertising campaigns between 1992 and 1997. Campaigns had to last for a minimum of 18 months</td>
<td>Monthly advertising expenditure for named DTCA drugs</td>
<td>A positive association (p&lt;0.05) between advertising expenditure, of data points included in analyses. Several data points available before and during the DTCA campaign</td>
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<td>Mintzes et al</td>
<td>Zachry et al</td>
<td>US primary care</td>
<td>DTCA mass media campaigns for five classes of prescription only medicines (antihistamines, antihypertensives, anti-ulcer drugs, benign prostatic hyper trophy (BPH) drugs, and cholesterol lowering drugs)</td>
<td>New diagnoses for the advertised drugs’ FDA approved indications</td>
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DTCA, direct to consumer advertising.
requests despite feeling ambivalent about the drug that was prescribed. Those who requested a specific DTCA drug were 16 times more likely to receive a drug than those who did not request a specific drug (OR 16.9, 95% CI 7.5 to 38.2).

No studies were found that examined the impact of DTCA on patient satisfaction with care, or the impact of DTCA and altered prescribing on actual health outcomes. There were also no studies that examined the cost effectiveness of DTCA by combining health outcomes and the economic costs of altered prescribing.

**DISCUSSION**

To our knowledge, this is the first application of a systematic review method in this area of practice and policy. Given the importance of DTCA and discussion that has taken place in the medical and lay press,2,5,22,25 we were surprised that the impact of this policy has not been subject to more extensive or rigorous evaluation. From the limited research available, our main conclusion is that DTCA does alter prescribing behaviour and volume. This conclusion is based on three interrupted time series studies and one comparative cross sectional study. Our review also highlights the fact that no studies have examined the impact of direct to consumer advertising on either health outcomes or examined the costs and health and social consequences of DTCA. These conclusions are based on a systematic evaluation of the research literature rather than an unsystematic (and potentially biased) overview.24

Proponents of DTCA claim that advertisements are a legitimate source of quality patient information.2 Informing and empowering patients are major themes in the UK and in many healthcare systems, and a case for DTCA might be argued to help develop a more informed and assertive population. Arguments against DTCA principally centre on concerns about the pharmaceutical industry’s ability to produce unbiased information. Given the nature of market economics, the primary aim of DTCA campaigns is to increase market share and profit rather than enhance well-being.25 Hence, advertisements may not look at all treatment options including non-drug treatments, or provide a consumer with comprehensive information on potential adverse effects. Concerns about the quality of information in advertisements are in many cases justified, with one in four products violating the basic regulations set down by the Food and Drug Administration.26

Hoffman and Wilkes,27 reflecting on the experience in the US, assert that DTCA “unreasonably increases consumer expectations, forces doctors to spend time disabusing patients of misinformation, diminishes the doctor-patient relationship because a doctor refuses to prescribe an advertised drug, or results in poor practice if the doctor capitulates and prescribes an inappropriate agent.”

The research presented in this review tends to support this assertion. No empirical research has demonstrated better communication and improved health outcomes. Given the lack of evidence of a beneficial effect on healthcare quality, concerns that DTCA undermines efforts to improve efficiency and cost-conscious prescribing—including use of generic drugs where branded drugs confer marginal benefit—appear well founded.

The results of the study conducted in the Netherlands also raises questions about the effects of industry funded disease awareness campaigns.28 The limited evidence available seems to suggest that such campaigns can increase market share and product awareness. Similarly, it does seem to create markets which did not previously exist by generating demand for treatments for non-life-threatening conditions about which the public has little awareness—such as fungal nail infections, social anxiety disorder,26 or female sexual dysfunction.27 From the perspective of the pharmaceutical industry, disease awareness campaigns may offer an alternative promotional approach in regions where DTCA is currently prohibited. However, from the perspective of healthcare systems and governments struggling to contain ever increasing drug budgets, campaigns to increase awareness of non-life-threatening conditions could generate demand for treatments which will ultimately divert time and resources away from other more important conditions.26 28 This is a topic where further research is clearly justified.

Since DTCA is currently banned in most parts of the world, legislators and policy makers will periodically revisit the issue of whether DTCA should be allowed. Similarly, there is a powerful lobby on the part of the pharmaceutical industry to allow DTCA. The main finding of this review is the identification of a void in terms of the evidence of the wider impact of DTCA – over and above increased prescriptions and market share. Policy making must therefore proceed in the absence of a definitive answer as to the specific consequences of DTCA on individual patient care and healthcare systems. The onus is on those who might support DTCA to produce evidence of benefit and, in the absence of this evidence, we must assume that the likely disbenefits (clinical and economic) outweigh the as yet unproven benefits. This opinion was reflected by Mintzes and colleagues,29 when they examined this issue for the benefit of the Canadian healthcare system. They concluded that: “We could find no evidence of improved drug utilization, improved doctor/patient relations, or reductions in hospitalization rates, serious morbidity or mortality attributable to DTCA. The aim of the prohibition of prescription drug advertising in Canada is health protection. Any legislative change that would weaken the current restrictions on such advertising should be based on strong evidence that concerns about potential harm are unfounded, and—ideally—evidence of health benefits. On the contrary, we found a considerable body of evidence suggesting that such concerns are warranted, and no evidence that DTCA is likely to improve the health.”

These are also the conclusions that can be drawn from the first systematic empirical overview of this topic.

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**Key messages**

- Direct to consumer advertising (DTCA) is currently allowed only in the US and New Zealand.
- Proponents suggest DTCA is a legitimate form of patient education with the potential for more informed patients and better healthcare.
- Opponents question the wisdom of DTCA, since it potentially distorts the patient-doctor relationship, rational health policies and prescribing practice, and generates demand without necessarily improving health outcomes.
- A systematic review of evidence of the clinical and economic consequences confirms that DTCA does influence patient demand and doctor prescribing behaviour. No evidence of health benefit was found since this had not been examined in any detail.
- Calls to allow DTCA should be resisted in the absence of any evidence of benefit from such an influence of prescribing behaviour.

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