

# Barriers to Australian physicians' and paediatricians' involvement in randomised controlled trials

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The randomised-controlled trial (RCT) is the best tool for evaluating the effects of interventions and providing the evidence for clinical and regulatory decision making.<sup>1,2</sup> There have been significant improvements in healthcare as a result of findings from clinical trials, but recruitment problems are common, particularly for paediatric trials,<sup>3</sup> and may cause delays, increased costs and failure to complete trials.<sup>4</sup> Doctor-related factors have been cited as one of the primary reasons for poor recruitment for clinical trials.<sup>5</sup>

Barriers to trial participation for doctors<sup>4,6,7</sup> include personal conflicts between the roles of clinician and scientist,<sup>8</sup> time and financial constraints,<sup>9</sup> lack of rewards,<sup>8</sup> perceived loss of autonomy,<sup>10</sup> problems complying with protocols,<sup>11</sup> discomfort with random allocation of patients to treatment,<sup>12</sup> preference for particular treatments,<sup>13</sup> difficulty with ethics requirements and informed consent,<sup>5</sup> concerns about patients' wellbeing,<sup>14</sup> and effects on the doctor-patient relationship.<sup>11,14</sup> Most previous studies on barriers for doctors' participation in RCTs focused on recruitment for oncology trials.<sup>15</sup>

The "Physician Orientation Profile" (POP) is a questionnaire designed to assess doctors' attitudes to treatment and RCTs. It has been used to survey 2691 cancer specialists in four separate published studies in the United States, Canada and the United Kingdom,<sup>8,12,15,16</sup> and one unpublished study in Australia.<sup>17</sup> It assesses five indices of physician attitudes and behaviour regarding RCTs: primary allegiance, decision-making under conditions of uncertainty, professional activities, perceived rewards, and peer-group influence.<sup>15</sup> Scores provided by this questionnaire range along a continuum, with low scores representing therapist (clinician-oriented) and high scores representing experimenter (research-oriented) attitudes, which are predictive of doctors' participation in RCTs.

Because little is known about Australian specialist-physicians' attitudes to trial participation, we used a modified POP to compare responses between Australian physicians and paediatricians.

## ABSTRACT

**Objective:** To compare attitudes of Australian physicians and paediatricians about treatment and randomised controlled trial (RCT) participation.

**Design and participants:** A cross-sectional survey using the validated "Physician Orientation Profile" (POP), with 250 physicians and 250 paediatricians surveyed.

**Outcome measures:** Five indices — primary allegiance, decision making under uncertainty, professional activities, perceived rewards, and peer-group influence — with scores for each participant ranging along a continuum from clinician-oriented to research-oriented and expressed as a number between 0 and 1.

**Results:** Overall response rate was 60%, with 135 physicians (54%) and 165 paediatricians (66%) responding. Paediatricians and physicians were similar in their attitudes to RCT participation, being generally clinician-oriented rather than research-oriented and less inclined to participate in RCTs when there is uncertainty about the best treatment. Most assign limited time to research, with 26.9% not currently involved in research and 31.5% having no experience of RCT participation. Doctors perceive few rewards and little peer-group influence regarding trial participation. Independent predictors of favourable attitudes to trial participation (based on POP scores) were the presence of allocated research time (0.37 for no allocated research time v 0.61 for > 70% research time;  $P < 0.0001$ ), previous experience enrolling a patient in an RCT (0.40 for no experience v 0.46 for experience;  $P < 0.0001$ ), and articles published in the past 12 months (0.40 for no publications v 0.55 for > 3 publications;  $P < 0.0001$ ).

**Conclusions:** This study highlights the minor importance of research for most Australian physicians. Research plays only a small role in their professional activities, and the importance of research participation is not recognised. They are clinician-oriented in their attitudes to RCT participation. To encourage greater involvement in trials among physicians in Australia, clinical research needs to be restructured in a primarily clinically oriented setting with dedicated research time.

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## METHODS

Five hundred doctors (250 physicians and 250 paediatricians) were randomly selected by computer (using the RAND worksheet function in Excel<sup>18</sup>) from the 7378 doctors registered as Fellows of the Royal Australasian College of Physicians (RACP) in May 2002. All Fellows were included (clinicians, non-clinicians or retired doctors). These doctors were mailed a questionnaire along with a prepaid envelope and response slip (which could be

sent back separately from the questionnaire for follow-up purposes). Doctors with an email address (80%) received an additional email invitation. Non-responders were contacted at least twice within 6 months (by email if available, or by letter).

## Questionnaire development

The two-part, self-administered questionnaire was based on the "Physician Orientation Profile" (POP).<sup>8,12,15,16</sup> We combined

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**1 Comparison of respondents' research experience**

Variable	Total respondents	Physicians	Paediatricians	P
Participants	300	134 (45.0%)	164 (55.0%)	
<b>Enrolled patients in a randomised controlled trial</b>				
Ever	295			
No	93 (31.5%)	31 (23.7%)	62 (37.8%)	0.009
In the last year	285			
0	128 (44.9%)	46 (35.9%)	82 (52.2%)	0.01
1–10	88 (30.9%)	42 (32.8%)	46 (29.3%)	
> 10	69 (24.2%)	40 (31.3%)	29 (18.5%)	
<b>Research time*</b>				
None	79 (26.9%)	36 (27.5%)	43 (26.4%)	0.5
< 30%	153 (52.0%)	68 (51.9%)	85 (52.1%)	
≥ 30%	62 (21.1%)	27 (20.7%)	35 (21.5%)	
<b>Articles published in the last year</b>				
None	129 (44.0%)	56 (42.7)	73 (45.1%)	0.7
≤ 3	108 (36.8%)	52 (39.7%)	95 (34.6%)	
> 3	56 (19.1%)	23 (17.6%)	33 (20.4%)	

\* By comparison, of the 3387 Australian physicians and 936 paediatricians who participated in the Clinical Workforce Surveys 2001,<sup>20</sup> 46.5% spent no time in research; the remainder spent a mean of 17% of their time in research (median, 10%; range, 1%–90%).

the items from the four previous published studies. Where wording of questions differed between studies, we chose the version that was most clear. We also excluded questions that were specific for oncology practice. Ten physicians and paediatricians piloted the original POP questionnaire for acceptability and content. After feedback, three questions were reworded for the Australian context, and two questions were added.

The first part of the questionnaire consisted of 11 items that served as predictors of doctors' treatment philosophies. These were demographic (age, sex) and practice details (practice specialty, professional appointment, clinical setting, location of practice, and number of patients seen per week) and research experience (previous experience with RCT participation, published articles and designated research time). The second part consisted of 33 items, which assessed the five indices of doctors' attitudes to treatment and RCTs (see Box 2). The questionnaire is available from the authors upon request.

Binary-option questions were used where possible in the questionnaire to ensure that the final score had high discriminative value. When participants wrote their own answer instead of choosing a given option, the response was matched to the closest

option given. A small number of answers were excluded because they did not match a given option. The POP scores for doctors' attitudes to treatment and RCTs were calculated by a similar method to that used in previous studies, where each item was assigned a score from 0 to 1, with pure "researcher or scientist" responses scoring 1 and pure "clinician or therapist" responses scoring 0.<sup>8,12,15</sup> The POP score was the mean of individual scores, and was derived by dividing the sum of individual scores by the number of questions answered and expressed as a number between 0 and 1 to ensure that the number of questions answered did not influence the mean score. In previous studies, doctors with higher POP scores were more research-oriented, reported higher past patient accrual to trials and showed greater intention to enter patients into trials in the future.<sup>12</sup>

**Statistical analysis**

A sample size of 500 was chosen (with 250 doctors in each group), which would allow the detection of statistically significant differences over a range of plausible proportions of responses to each question.

Demographic and practice variables and response to individual questions were compared between physicians and paediatricians

using  $\chi^2$  for differences in proportions. POP scores were compared across demographic and practice variables using analysis of variance (ANOVA) for differences in means. Backwards stepwise regression of the variables found to be significant ( $P < 0.05$ ) on univariate analysis was performed to identify independent predictors of POP score. The SPSS statistical package<sup>19</sup> was used for data analysis.

**Ethical approval**

This project was approved by the ethics committee of the Children's Hospital at Westmead and was supported by the Royal Australasian College of Physicians.

**RESULTS****Demographics and practice details**

Three hundred doctors returned completed questionnaires (60% response rate). Significantly more paediatricians responded (55% v 45%;  $P = 0.004$ ). Most respondents were male (72.8%) and practised in an urban setting (87.2%). The median age was 47 years (range, 32–94 years). Doctors worked in private practice (28.9%), teaching hospitals (53.7%) or both (6.4%), with 11.1% working in other settings. Appointments were in private practice (33.1%), as salaried hospital staff specialists (44.8%), academics (11.4%) or other (10.7%, all non-clinical). Those contacted by email were significantly more likely to participate in the questionnaire (65% v 39%;  $P = 0.0001$ ).

**Research experience**

Many respondents (26.9%) were not currently involved in any research (Box 1), and 78.9% spent less than 30% of their time on research activities; 56% had had an article published in the past 12 months. Nearly a third of respondents (31.5%) reported no experience with enrolling a patient in an RCT, and 44.9% had not enrolled a patient within the previous year.

**Comparison between paediatricians and physicians**

There were few differences between the paediatricians and physicians. There were more hospital staff specialists (51.5% v 36.2%;  $P < 0.01$ ) and females (34.1% v 17.9%;  $P < 0.004$ ) among the paediatricians. Although research time and publication experience were similar in the two groups, fewer paediatricians had experience with

## RESEARCH

### 2 Physicians' and paediatricians' responses to questions on primary allegiance and decision-making under conditions of uncertainty

	Physicians (% [95% CI])	Paediatricians (% [95% CI])	Total (% [95% CI])
<b>Q12. Although many doctors are expected to perform both tasks, as a doctor my primary commitment is to:</b>			
Future generations of patients (society)	8.5 (4.3–14.6)	12.9 (8.2–19.0)	10.9 (7.5–14.5)
Present patients (individual)	88.5 (81.7–93.4)	84.0 (77.5–89.3)	86.0 (82.0–90.0)
<b>Q14. If I had to choose, I would say my primary task is:</b>			
Caring for individual patients	90.8 (84.4–95.1)	90.0 (84.3–94.2)	90.3 (86.3–93.5)
Contributing to scientific knowledge	9.2 (4.9–15.6)	10.0 (5.8–15.7)	9.7 (6.5–13.7)
<b>Q21. I would like to assess how successful I was as a physician by:</b>			
My research contribution	17.7 (11.6–25.4)	11.9 (7.4–18.0)	14.5 (10.5–18.6)
How I helped individual patients	74.6 (66.2–81.8)	78.6 (71.4–84.7)	76.8 (72.0–81.7)
Both	7.7 (3.8–13.7)	9.4 (5.4–15.1)	8.7 (5.6–12.5)
<b>Q22. I would rather be somewhat:</b>			
Too involved with my patients	85.8 (78.3–91.5)	84.4 (77.4–89.8)	85.0 (80.7–89.3)
Too detached from my patients	14.2 (8.5–21.7)	15.6 (10.2–22.5)	15.0 (10.7–19.3)
<b>Q23. If a patient refuses to participate in a randomised clinical trial, I would:</b>			
Treat the patient off the study	100.0 (97.1–100)	98.7 (95.5–99.9)	99.3 (97.5–99.9)
Refer the patient to another doctor	0	1.3 (0.2–4.5)	0.7 (0.1–2.6)
<b>Q24. I would rather be known for:</b>			
My interpersonal skills with patients	78.1 (70.0–84.9)	77.0 (69.7–83.3)	77.5 (72.7–82.3)
My research accomplishments	20.3 (13.7–28.3)	18.0 (12.4–24.8)	19.0 (14.5–23.6)
<b>Q25. Overall I feel the quality of patient care:</b>			
Increases when a patient is in a clinical trial	46.1 (37.3–55.1)	44.3 (36.4–52.4)	45.1 (39.3–50.9)
Decreases when a patient is in a clinical trial	6.3 (2.7–11.9)	3.2 (1.0–7.2)	4.5 (2.4–7.7)
Does not change when a patient is in a clinical trial	47.7 (38.8–56.7)	52.5 (44.4–60.5)	50.3 (44.6–56.1)
<b>Q27. Randomised clinical trials restrict my ability to individualise patient care:</b>			
True	26.8 (19.3–35.4)	28.1 (21.3–35.8)	27.5 (22.4–32.7)
Makes no difference	73.2 (64.7–80.7)	71.9 (64.2–78.7)	72.5 (67.3–77.6)
<b>Q31. When a potentially eligible patient chooses not to enroll on a trial that I have suggested:</b>			
I often feel disappointed	28.8 (21.1–37.6)	27.3 (20.4–35.0)	28.0 (22.7–33.2)
I seldom feel disappointed	71.2 (62.4–78.9)	72.7 (65.0–79.6)	72.0 (66.8–77.3)
<b>Q43. I think the patient's right to select treatment options is always more important than the advancement of scientific knowledge:</b>			
True	71.1 (62.4–78.8)	69.0 (61.2–76.1)	69.9 (64.6–75.2)
<b>Q13. When there is controversy in the literature as to which treatment is best:</b>			
I enter the patient in a clinical trial if one exists	40.7 (31.9–49.9)	31.8 (24.6–39.8)	35.7 (30.1–41.4)
I personally select a treatment for the patient	57.7 (48.5–66.6)	66.2 (58.2–73.6)	62.5 (56.8–68.2)
<b>Q17. When making critical and controversial decisions, I usually:</b>			
Seek major input from my patients	92.9 (87.0–96.7)*	98.1 (94.6–99.6)*	95.8 (92.8–97.8)
Do not seek major input from my patients	7.1 (3.3–13.0)	1.9 (0.4–5.4)	4.2 (2.2–7.2)
<b>Q26. When published data and my clinical judgement conflict, I am more likely to rely on:</b>			
My clinical experience	44.2 (35.5–53.2)	44.9 (37.0–53.0)	44.6 (38.8–50.4)
Published data	53.5 (44.5–62.3)	53.8 (45.7–61.8)	53.7 (47.9–59.4)
<b>Q33. When a protocol includes a treatment that is more aggressive than I would usually give to similar non-trial patients:</b>			
I am often reluctant to participate	51.2 (42.0–60.3)	51.7 (43.4–59.9)	51.5 (45.5–57.4)
It makes no difference	48.8 (39.7–58.0)	48.3 (40.1–56.6)	48.5 (42.6–54.5)
<b>Q34. When a protocol includes a treatment that is less aggressive than I would usually give to similar non-trial patients:</b>			
I am often reluctant to participate	44.3 (35.3–53.5)	36.4 (28.8–44.6)	39.9 (34.1–45.7)
It makes no difference	55.7 (46.5–64.7)	63.6 (55.4–71.2)	60.1 (54.3–65.9)
<b>Q35. I am reluctant to participate in a trial that may randomise the patient to a "no treatment" group:</b>			
Yes	36.2 (27.9–45.2)*	21.5 (15.4–28.7)*	28.1 (22.9–33.3)
<b>Q40. When I am personally uncertain as to which treatment is best, I am likely to:</b>			
Enter the patient in a randomised clinical trial if I am aware one exists	57.3 (48.1–66.1)	53.5 (45.4–61.6)	55.2 (49.4–61.0)
Personally select a treatment	42.7 (33.9–51.9)	46.5 (38.4–54.6)	44.8 (39.0–50.6)

\* Difference significant at  $P < 0.05$ .

enrolling patients in trials (62.2% v 76.3%;  $P < 0.009$ ).

### Responses to the five indices of doctors' attitudes to involvement in RCTs

**Primary allegiance** (Box 2): The primary allegiance of most doctors was caring for individual patients. Relationships with patients were valued over research accomplishments and most felt that patients' right to select treatments took precedence over advancing knowledge. A small group of respondents (5%; question [Q] 25) thought that the overall quality of patient care would decrease for trial participants and 27% (Q 27) thought that RCTs restricted their ability to individualise patient care.

**Decision-making under conditions of uncertainty** (Box 2): When published data and clinical judgement conflicted, 54% of respondents claimed they would rely on published data (Q 26). When there was controversy in the literature regarding the best treatment, most respondents preferred to personally select a treatment, with only 35% being willing to refer a patient for trial participation (Q 13). However, 54% were willing to refer a patient if they were personally uncertain about treatments (Q 40). Most would seek major input from the patient when making critical or controversial decisions (Q 17). More respondents were reluctant to participate in a trial involving a protocol that included a treatment that was more aggressive than their usual treatment (Q 33) compared with one involving a less aggressive treatment (Q 34); 28% were reluctant to participate in a trial involving a placebo (Q 35).

**Professional activities** (Box 3): Research plays a small role in most respondents' professional activities (Q 19, Q 32, Q 42). Although most were willing to enter some patients into RCTs, only 25% would enter most, and 12% would enter all, of their potentially eligible patients (Q 18).

**Perceived rewards** (Box 3): Respondents perceived more rewards for clinical skills than contribution to scientific knowledge (Q 15) and thought that trial participation made no difference to their patient population (Q 44), although some (45%; Q 39) thought trial involvement might enhance their reputation. The laborious recruitment process (Q16, Q37), detailed monitoring of their management of trial patients (Q 29), increased paperwork (Q 30) and lack of

financial rewards (Q 38, Q 41) were significant deterrents for trial participation for some participants.

**Peer-group influence** (Box 3): Most respondents (63%; Q 36) reported not being affected by the opinions of referring doctors about trial participation, and most perceived little pressure from their institution to participate in trials (Q 28).

### Comparison between paediatricians and physicians

Responses to individual questions on treatment philosophies were similar between paediatricians and physicians. However, physicians were more reluctant to participate in RCTs involving placebos (36.2% v 21.5%;  $P < 0.006$ ; Q 35), more frequently thought trial participation affected their patient population (16.2% v 6.9%;  $P < 0.04$ ; Q 44) and more often identified financial benefits for their institution or department as a reason for trial participation (15.9% v 5.7%;  $P < 0.005$ ; Q 38).

### Comparison of doctor demographics and research experience with POP score

These comparisons are shown in Box 4. The mean POP score for respondents was 0.44 (95% CI, 0.43–0.46). There was no significant difference in POP scores between physicians and paediatricians, or between males and females. Univariate analysis showed that doctors who were younger, in salaried positions or in urban settings and saw fewer patients had higher POP scores (ie, were more research-oriented) than doctors who were older, or in private or rural practice. Research involvement (ie, experience with enrolling patients in trials, time assigned to research activities and number of articles published in the past year) also correlated with higher POP scores. There were linear relationships between number of patients who participated in an RCT in the past year, amount of research time, number of articles published in the past year, and number of patients seen per week (after deleting doctors who did not see any patients) and the POP score — lower number of patients seen per week, higher patient participation in trials and increased publications correlated with higher POP scores. On multivariate analysis, three independent variables were found to significantly predict POP scores. These were allocated research time (0.050; 95% CI, 0.036–0.064;  $P < 0.0001$ ), history

of enrolling a patient in an RCT in the past year (0.022; 95% CI, 0.007–0.037;  $P = 0.005$ ), and articles published in the past 12 months (0.012; 95% CI, 0.003–0.022;  $P = 0.012$ ). The overall correlation coefficient ( $R^2$ ) for the model was 0.351 (ie, 35.1% of the variability in respondent's POP score can be explained by these three variables).

## DISCUSSION

We found that attitudes and behaviours between Australian physicians and paediatricians are similar, with a clinician-oriented focus. Doctors' primary allegiance is to the individual patient, with less inclination to participate in RCTs when there is uncertainty about the best treatment. Professional activities tend to be clinically focused, with most participants assigning limited time for research. Doctors reported few rewards and little peer-group influence in trial participation.

The demographic details and practice settings of our respondents, with a predominance of males in an urban setting, were similar to those of the clinical workforce surveys of 2001 for Australian specialist physicians,<sup>20</sup> showing that our data are representative of the Australian workforce. There were more hospital staff specialists and females among the paediatricians, reflecting the practice trend in Australia.<sup>20</sup> Doctors in private practice also appear to be under-represented among our respondents compared with the Australian clinical workforce surveys. However, it is difficult to compare the results, as how practice appointment is measured differs.<sup>20</sup>

The strong correlation between research experience and doctors' attitudes to trials as expressed by POP scores was not surprising and is supported by our previous study, which showed that doctors with research experience perceived most benefits for trial participation and those in private practice the least.<sup>21</sup> However, our cross-sectional study design did not allow us to determine whether doctors with positive attitudes to trials were more likely to participate in research activities, or whether research experience changed doctors' attitudes to trials, or both.

The relatively low variability in POP scores explained by the three independent variables (allocated research time, experience with enrolling a patient in an RCT and publications in the past year) suggests that other factors, not measured in the study,

## 3 Physicians' and paediatricians' responses to questions on professional activities, perceived rewards and peer-group influence

	Physicians (% [95% CI])	Paediatricians (% [95% CI])	Total (% [95% CI])
<b>Q18.</b> Ideally I would like to refer or enter the following proportion of my potentially eligible patients into randomised clinical trials:			
None	2.4 (0.5–6.8)	3.8 (1.4–8.1)	3.2 (1.5–6.0)
Some	57.1 (48.0–65.9)	51.3 (43.2–59.4)	53.9 (48.1–59.7)
Half	8.7 (4.4–15.1)	2.6 (0.7–6.4)	5.3 (3.0–8.6)
Most	23.0 (16.0–31.4)	26.9 (20.1–34.6)	25.2 (20.1–30.2)
All	8.7 (4.4–15.1)	15.4 (10.1–22.0)	12.4 (8.6–16.3)
<b>Q19.</b> The time I devote to publications, lectures and research commitments, compared to clinical work, is relatively:			
Totally clinical work	12.7 (7.4–19.8)	9.5 (5.4–15.2)	10.9 (7.3–14.5)
Mainly clinical work	61.1 (52.0–69.7)	61.4 (53.3–69.0)	61.3 (55.6–66.9)
Clinical and research equally	14.3 (8.7–21.6)	20.9 (14.8–28.1)	18.0 (13.5–22.4)
Mainly research	7.9 (3.9–14.1)	7.6 (4.0–12.9)	7.7 (4.9–11.5)
Totally research	4.0 (1.3–9.0)	0.6 (0.0–3.5)	2.1 (0.8–4.5)
<b>Q32.</b> Frequent publications are important to my career advancement:			
Yes	46.6 (37.8–55.5)	46.9 (39.0–54.9)	46.8 (41.0–52.5)
<b>Q42.</b> I am more likely to attend a conference that focuses on:			
Clinical issues	76.2 (67.9–83.2)	73.1 (65.6–79.8)	74.5 (69.5–79.5)
Research issues	20.0 (13.5–27.9)	23.1 (16.8–30.4)	21.7 (17.0–26.5)
<b>Q15.</b> In my hospital, doctors are given more reward for:			
Clinical skills with patients	69.4 (60.4–77.5)	64.3 (56.3–71.8)	66.5 (61.0–72.1)
Contributing to scientific knowledge	28.1 (20.3–37.0)	34.4 (27.0–42.4)	31.7 (26.2–37.1)
<b>Q16.</b> If written informed consent was not required, I would approach more patients to enter clinical trials			
True	10.4 (5.7–17.1)	8.7 (4.8–14.2)	9.4 (6.3–13.4)
Makes no difference	89.6 (82.9–94.3)	91.3 (85.8–95.2)	90.6 (86.6–93.7)
<b>Q20.</b> My income is dependent on my research activities:			
Yes	12.2 (7.1–19.1)	8.7 (4.8–14.2)	10.3 (6.8–13.8)
No	87.8 (80.9–92.8)	91.3 (85.8–95.2)	89.7 (86.2–93.2)
<b>Q29.</b> The need for detailed monitoring of my management of trial patients by trial staff deters me from participating in randomised clinical trials:			
Yes	11.1 (6.2–17.9)	10.0 (5.8–15.7)	10.5 (6.9–14.0)
<b>Q30.</b> The increased paperwork involved in treating patients on trials deters me from participating in randomised clinical trials:			
Yes	39.4 (30.8–48.4)	36.3 (28.8–44.2)	37.6 (32.0–43.2)
<b>Q37.</b> The thought of having to spell out all the details of a trial to eligible patients discourages me from approaching them to participate:			
True	22.0 (15.2–30.3)	17.5 (12.0–24.3)	19.5 (14.9–24.1)
<b>Q38.</b> A major reason for my participation in randomised clinical trials is that it financially benefits my institution or department:			
Agree	15.9 (10.0–23.4)*	5.7 (2.7–10.6)*	10.2 (6.7–13.8)
<b>Q39.</b> Overall, involvement in randomised clinical trials:			
Enhances my reputation	48.4 (39.5–57.4)	41.3 (33.5–49.5)	44.5 (38.7–50.3)
Does not enhance my reputation	51.6 (42.6–60.5)	58.7 (50.5–66.5)	55.5 (49.7–61.3)
<b>Q41.</b> If research activities were to enhance my income, I would enter more patients in randomised clinical trials:			
Agree	28.3 (20.7–37.0)	22.5 (16.3–29.8)	25.1 (20.1–30.1)
<b>Q44.</b> When I participate in a randomised clinical trial, it is more likely that:			
I increase my patient population	8.1 (4.0–14.4)*	2.5 (0.7–6.4)*	5.0 (2.8–8.2)
I lose patients I might otherwise keep	8.1 (4.0–14.4)	4.4 (1.8–8.9)	6.0 (3.6–9.5)
It makes no difference to my patient population	83.7 (76.0–89.8)	93.0 (87.9–96.5)	89.0 (85.3–92.6)
<b>Q28.</b> In my hospital the pressure to participate in a randomised clinical trial is relatively:			
Low	87.5 (80.2–92.8)	89.9 (84.2–94.1)	88.9 (85.2–92.6)
High	12.5 (7.2–19.8)	10.1 (5.9–15.8)	11.1 (7.4–14.8)
<b>Q36.</b> The opinions of the patient's usual doctor regarding randomised clinical trials affects my decision to approach an eligible patient:			
True	37.9 (29.3–47.0)	35.9 (28.4–44.0)	36.8 (31.1–42.4)

\* Difference significant at  $P < 0.05$ .

#### 4 Comparison of Physician Orientation Profile (POP) score by 296 doctors' demographics and research experience

Demographic details	No. responses	Mean POP score (95% CI)	P
Age (years)			0.005
0–39	67	0.49 (0.46–0.51)	
40–49	111	0.43 (0.41–0.46)	
50–59	75	0.45 (0.42–0.47)	
≥ 60	43	0.41 (0.37–0.46)	
Oncologists versus non-oncologists			0.03
Oncologists	12	0.52 (0.41–0.63)	
Non-oncologists	285	0.44 (0.43–0.45)	
Appointment			0.0001
Staff specialist/academics	163	0.47 (0.45–0.49)	
VMO/private practice	97	0.40 (0.38–0.42)	
Primary setting			0.0001
Salaried	180	0.47 (0.45–0.49)	
Fee for service	86	0.38 (0.36–0.41)	
Location of practice			0.0001
Urban	252	0.45 (0.44–0.47)	
Rural	37	0.38 (0.35–0.40)	
Patients seen per week			0.002
None	25	0.42 (0.35–0.50)	
1–20	78	0.49 (0.46–0.52)	
21–50	106	0.44 (0.42–0.46)	
51–100	79	0.41 (0.39–0.43)	
> 100	6	0.37 (0.23–0.51)	
Previously enrolled patients in RCT			0.0001
No	93	0.40 (0.37–0.43)	
Yes	203	0.46 (0.45–0.48)	
Patients enrolled in RCT in the last year*			0.0001
0	128	0.41 (0.39–0.43)	
1–10	88	0.44 (0.42–0.46)	
> 10	70	0.50 (0.47–0.53)	
Research time*			0.0001
None	79	0.37 (0.36–0.39)	
< 30% research	154	0.44 (0.42–0.46)	
30%–50% research	34	0.53 (0.49–0.56)	
50%–70% research	11	0.56 (0.50–0.62)	
> 70% research	17	0.61 (0.56–0.66)	
Articles published in the last year*			0.0001
0	129	0.40 (0.38–0.41)	
1	35	0.45 (0.41–0.49)	
2	47	0.45 (0.41–0.48)	
3	27	0.47 (0.42–0.52)	
> 3	56	0.55 (0.51–0.58)	

Mean POP score ranges from 0–1, with 1 indicating an extreme researcher, and 0 indicating an extreme clinician. RCT = randomised controlled trial. VMO = visiting medical officer.

\*Independent variables found to significantly predict POP scores on multivariate analysis.

play an important role in determining doctors' attitudes to trials (such as doctors' medical training and training in research, opportunity to enrol patients in trials, personal experiences, cultural differences, personality differences and attitudes about healthcare). These factors are difficult to measure and quantify.

Recruitment to paediatric trials (with the exception of oncology) is usually thought to be more difficult.<sup>3,22,23</sup> The finding that physicians and paediatricians were similar in their attitudes to RCTs is interesting, because it suggests that factors other than doctors' attitudes to trial participation may explain the difference in recruitment between adult and paediatric trials. Limited experience with RCTs among paediatricians may reflect less opportunity to participate in paediatric trials, which are less common than adult trials.<sup>3,24,25</sup>

#### Limitations

We were unable to obtain practice and demographic data for non-respondents. Comparison with Australian workforce data obtained from 2001 suggests that our sample under-represented doctors in private practice. More respondents in our study reported involvement in research compared with the Australian clinical workforce (46.5% v 26.9%), although the questions by which these data were elicited were somewhat different.<sup>17</sup> Despite efforts to minimise non-response bias, it is likely that our results overestimate the research orientation of Australian specialist-physicians, who are probably even more clinician-oriented than our findings suggest.

As the RACP database did not provide information on status of clinical practice, our sample included doctors who were not in active clinical practice. Response from practising clinicians may differ significantly from those not in clinical practice, as was shown in our study.

#### Conclusions

The crisis in clinical research is recognised worldwide and has been highlighted by the Clinical Research Roundtable in the US<sup>26</sup> and by the National Health and Medical Research Council in Australia.<sup>27</sup> Taskforces have been formed to address this issue.

We identified lack of research experience and opportunities for research as factors affecting doctors' attitudes, and this may explain why research has a low priority for

clinicians. Australian doctors are clinician-oriented rather than research-oriented in their attitudes to RCT participation, highlighted by their personal preference for selecting treatment rather than referring for trial participation in the face of treatment uncertainty. Research plays only a small role in their professional activities, and the importance of research participation is undervalued.

Future research is needed to further explore Australian specialist-physicians' views, attitudes and barriers to participation in RCTs and to promote a positive attitude to trials and trial participation, particularly among doctors in private or rural practice. Strategies for providing the necessary time, resources and opportunities for research while reducing the workload for trial participation are needed. It is unclear whether the mandatory research projects of the RACP for Fellowship accreditation, which are designed to foster research interest, have been effective. The problems in clinical research are unlikely to be resolved unless the role of research is restructured in a primarily clinically oriented setting.

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## COMPETING INTERESTS

None identified.

## REFERENCES

- National Health and Medical Research Council. How to review the evidence: systematic identification and review of the scientific literature. Handbook series on preparing clinical practice guidelines. Canberra: NHMRC, 1999.
- Barton S. Which clinical studies provide the best evidence? The best RCT still trumps the best observational study. *BMJ* 2000; 321: 255-256.
- Caldwell PHY, Murphy SB, Butow PB, et al. Clinical trials in children. *Lancet* 2004; 364: 803-811.
- Lovato LC, Hill K, Hertert S, et al. Recruitment for controlled clinical trials: literature summary and annotated bibliography. *Control Clin Trials* 1997; 18: 328-352.
- Siminoff LA, Zhang A, Colabianchi N, et al. Factors that predict the referral of breast cancer patients onto clinical trials by their surgeons and medical oncologists. *J Clin Oncol* 2000; 18: 1203-1211.
- Prescott RJ, Counsell CE, Gillespie WJ, et al. Factors that limit the quality, number and progress of randomised controlled trials. *Health Technol Assess (Washington DC)* 1999; 3(20): 1-143.
- Hunninghake DB, Darby CA, Probstfield JL. Recruitment experience in clinical trials: literature summary and annotated bibliography. *Control Clin Trials* 1987; 8(4 suppl): 6S-30S.
- Taylor KM. Integrating conflicting professional roles: physician participation in randomized clinical trials. *Soc Sci Med* 1992; 35: 217-224.
- Viability of cancer clinical research: patient accrual, coverage, and reimbursement. American Medical Association Council on Scientific Affairs. *J Natl Cancer Inst* 1991; 83: 254-259.
- Taylor KM, Shapiro M, Soskolne CL, Margolese RG. Physician response to informed consent regulations for randomized clinical trials. *Cancer* 1987; 60: 1415-1422.
- Taylor KM, Margolese RG, Soskolne CL. Physicians' reasons for not entering eligible patients in a randomized clinical trial of surgery for breast cancer. *N Engl J Med* 1984; 310: 1363-1367.
- Taylor KM, Feldstein ML, Skeel RT, et al. Fundamental dilemmas of the randomized clinical trial process: results of a survey of the 1737 Eastern Cooperative Oncology Group investigators. *J Clin Oncol* 1994; 12: 1796-1805.
- Benson AB, Pregler JP, Bean JA, et al. Oncologists' reluctance to accrue patients onto clinical trials: an Illinois Cancer Center study. *J Clin Oncol* 1991; 9: 2067-2075.
- Swanson GM, Ward AJ. Recruiting minorities into clinical trials: toward a participant-friendly system. *J Natl Cancer Inst* 1995; 87: 1747-1759.
- Fallowfield L, Ratcliffe D, Souhami R. Clinicians' attitudes to clinical trials of cancer therapy. *Eur J Cancer* 1997; 33: 2221-2229.
- Taylor KM, Kelner M. Interpreting physician participation in randomized clinical trials: the Physician Orientation Profile. *J Health Soc Behav* 1987; 28: 389-400.
- Ellis PM. Barriers to clinical trials for breast cancer: an investigation of doctors' attitudes towards randomised clinical trials [PhD Treatise]. The University of Sydney, 1997.
- Microsoft Excel [computer program]. Version 2000. US: Microsoft Corporation, 2000.
- SPSS statistical package [computer program]. Version 11.0 for Windows. Chicago, SPSS Inc, 2001.
- Dent O. Clinical workforce surveys 2001: clinical workforce in internal medicine and paediatrics in Australia 2001. Sydney: Royal Australasian College of Physicians, 2001.
- Caldwell PHY, Butow PN, Craig JC. Paediatricians' attitudes to randomized controlled trials involving children. *J Pediatr* 2002; 141: 798-803.
- Collet JP, Floret D, Cochat P, et al. Group meetings for recruitment of children in a clinical trial. *Therapie* 1991; 46: 139-142.
- Bleyer WA. Re: recruiting minorities into clinical trials: toward a participant-friendly system [letter]. *J Natl Cancer Inst* 1996 Mar 20; 88: 377.
- Campbell H, Surry SAM, Royle EM. A review of randomised controlled trials published in Archives of Disease in Childhood from 1982-96. *Arch Dis Child* 1998; 79: 192-197.
- Committee on Drugs, American Academy of Pediatrics. Guidelines for the ethical conduct of studies to evaluate drugs in pediatric populations. *Pediatrics* 1995; 95: 286-294.
- Association of American Medical Colleges. Breaking the scientific bottleneck. Clinical research: a national call to action. Available at: [www.aamc.org/research/calltoaction.htm](http://www.aamc.org/research/calltoaction.htm) (accessed Dec 2004).
- National Health and Medical Research Council. Health and Medical Research Strategic Review — implementation of the government's response. Canberra: AusInfo, 2001: 19-20.

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