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# Medicine in the marketplace: clinician and patient views on commercial influences on assisted reproductive technology

## BIOGRAPHY

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## KEY MESSAGE

ART experts and patients considered that commercial forces have positive and negative influences on ART provision, and that regulatory reforms and organizational cultural initiatives are needed as means to ensure patient well-being. The findings should be examined for insights into how best to govern ART and other commercialized healthcare services.

## ABSTRACT

**Research question:** What are the views and experiences of patient and expert stakeholders on the positive and negative impacts of commercial influences on the provision of assisted reproductive technology (ART) services, and what are their suggestions for governance reforms?

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## KEYWORDS

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**Design:** Semi-structured interviews were conducted with 31 ART industry experts from across Australia and New Zealand and 25 patients undergoing ART from metropolitan and regional Australia, between September 2020 and September 2021. Data were analysed using thematic analysis.

**Results:** Expert and patient participants considered that commercial forces influence the provision of ART in a number of positive ways – increasing sustainability, ensuring consistency in standards and providing patients with greater choice. Participants also considered commercial forces to have a number of negative impacts, including increased costs to government and patients; the excessive use of interventions that lack sufficient evidence to be considered part of standard care; inadequately informed consent (particularly with regard to financial information); and threats to patient–provider relationships and patient-centred care. Participants varied in whether they believed that professional self-regulation is sufficient. While recognizing the benefits of commercial investment in healthcare, many considered that regulatory reforms, as well as organizational cultural initiatives, are needed as means to ensure the primacy of patient well-being.

**Conclusions:** The views expressed in this study should be systematically and critically examined to derive insights into how best to govern ART. These insights may also inform the design and delivery of other types of healthcare that are provided in the private sector.

## INTRODUCTION

In many countries, assisted reproductive technology (ART) is provided partially or primarily in the private sector. This is the case in Australia, where most ART is provided in the private sector, with the market projected to reach $800 million in revenues in 2024 (*IBISWorld, 2023*). This includes large corporate clinics, some of which are owned by Australian or overseas private equity companies, some of which are listed on the Australian stock exchange (Supplementary Appendix A). The industry in Australia is heavily supported by the Australian government, which subsidizes an unlimited number of IVF cycles for eligible couples through the Medicare system (*Australian Government Department of Health, 2020*), although patients are still required to contribute co-payments (*Gorton, 2019*).

It has been argued that the provision of ART within the private sector reduces costs to government, makes ART services available to more people, provides patients with greater choice and encourages innovation (*Frith, 2018*; *Patrizio et al., 2022*). In this regard, it is noteworthy that Australia's largely private ART system adheres to high clinical standards (*Fertility Society of Australia and New Zealand, 2021*; *National Health and Medical Research Council, 2017*) and performs well in international comparisons of safety, quality and efficacy (*Chambers et al., 2021*). These standards are monitored through both external guidelines and a self-regulatory accreditation programme.

Concerns have been raised, however, about the effects of commercial influences on service provision, including the pricing and costs of ART services both to individuals and to payers (*Gleicher et al., 2019*; *Patrizio et al., 2022*), and the use of IVF in patients for whom other options are available and have not been tried, and patients for whom success is unlikely (*Australian Government Department of Health, 2020*). There have also been criticisms of the use of interventions that do not have sufficient evidence to be considered part of standard care and/or carry psychological, financial and biomedical harms (*Gleicher et al., 2019*; *Heneghan et al., 2016*; *Jeve et al., 2018*), marketing practices (*Australian Competition and Consumer Commission (ACCC), 2016*; *Heneghan et al., 2016*; *Lensen et al., 2021*), potential conflicts of interest (*Blakely et al., 2019*; *Patrizio et al., 2022*) and relationships between ART services and other health-related industries, such as diagnostic services and pharmaceutical companies (*Farquhar et al., 2017*). Commercial clinics' promotion of fertility preservation, particularly 'egg freezing', has also been a subject of public and professional debate (*Bruch et al., 2020*; *Van De Wiel, 2020*). A systematic review of the effect of corporatization of healthcare in the USA found that it was often accompanied by increased costs for patients and payers and by mixed or negative effects on quality (*Borsa et al., 2023*).

Reservations have also been expressed about the adequacy of professional self-regulation in privatized medical services such as ART (*Alonso et al., 2021*; *Wilkinson et al., 2019*). These kinds of concern have prompted reviews of ART policy and practice, for example the 2017 South Australian review of the Assisted Reproductive Treatment Act 1988 (SA) (*Allan, 2017*) and the 2018 review of the Victorian regulatory framework for ART (*Gorton, 2019*). Other recent reviews include the 2019 inquiry into ART practices by the Victorian Health Care Complaints Commissioner (*Health Care Complaints Commissioner Victoria, 2020*) and the Taskforce Report on Gynaecology MBS [Medicare Benefits Schedule] Items (*Australian Government Department of Health, 2020*). Among the conclusions of these reviews was that the self-regulatory regime lacks external accountability and, on its own, cannot be relied upon to ensure patient safety and service quality (*Allan, 2017*; *Gorton, 2019*).

Given the concerns about commercial influences on ART, it is important to understand the perspective of all relevant stakeholders about these issues. This article provides a high-level summary of the findings of a National Health and Medical Research Council-funded study involving in-depth interviews with a wide range of stakeholders including clinicians, embryologists, managers, regulators and patients, eliciting their views about commercial influences on ART. The study aims to inform strategies for governing ART that ensure the primacy of the patient's well-being while recognizing the benefits of commercial investment in healthcare. The study also aims to advance understanding of the implications of commercialized healthcare more broadly, with ART being just one of many domains of practice that are increasingly commercialized.

## MATERIALS AND METHODS

### Sampling strategy

The goal of the study was to identify the widest possible range of expert and patient perspectives. To achieve this, views were sought from a broad range of stakeholders, including ART specialists, nurses, counsellors, embryologists, clinical

managers, referring practitioners, regulators and patients who were seeking ART for a variety of reasons and were at various stages of the ART process, from both metropolitan and regional/rural areas.

### Recruitment

#### *Expert participants*

Eighteen participants were recruited via an invitation circulated to the ART community on the project's behalf by the influential ART professional body, the Fertility Society of Australia and New Zealand (FSANZ). A further 11 participants were recruited using investigators' professional networks, and two participants were identified by other participants. Follow-up interviews were conducted with 16 of the original participants to explore emergent issues in greater depth.

#### *Patient participants*

Patients were recruited using advertisements circulated via Twitter and through Facebook (paid and promoted), which invited them to express interest via a survey. To reach a regional audience, a press release was published alongside an advertisement in several regional newspapers.

For each group, recruitment ceased when 'thematic saturation' was achieved, that is, when additional participants' data yielded no significant new themes.

### Data collection

Interviews were conducted between September 2020 and September 2021 by three trained qualitative researchers (S.A., A.S. and E.S.), using the Zoom videoconferencing platform. Interviews were semi-structured and designed to elicit participants' experiences and views about (i) types of commercial influences on ART, (ii) their positive and negative impacts, (iii) how stakeholders deal with these influences, and (iv) the need for regulatory, clinical and/or organizational reform. Experts were also asked about their professional experiences and the moral and professional obligations of ART providers, and patients were asked about their experience of care (Supplementary Appendixes B and C). Interviews lasted between 38 and 155 min (mean 79 min). Interviews were audio-recorded, except in the case of one expert who declined recording but allowed field notes to be gathered.

Audio recordings were professionally transcribed verbatim and anonymized and pseudonymized prior to analysis, with removal of names and other potentially identifying information.

### Analysis

Data were analysed using thematic analysis (*Braun et al., 2019*) (Supplementary Appendix D). A coding framework was derived from the data, and codes were organized into domain summaries (accounts of what participants had to say about a topic) and then into categories aligned with the research questions.

Data collection and analysis proceeded in parallel, directing iterative revisions of the interview schedule. For each of the expert and patient datasets, two researchers undertook independent coding of the entire dataset. Other researchers conducted a more focused thematic analysis. The coders met regularly to identify areas of convergence and agree on the themes and domain summaries that were common to both datasets. The study reports the perspectives held in common by the experts and patients unless there is a meaningful divergence of views.

### Ethics

The study was approved by the University of Sydney Human Research Ethics Committee (Reference 2020/320, 21 May 2020). Participants either gave written consent or had verbal consent recorded at the time of interview.

## RESULTS

Interviews were conducted with 31 ART clinicians, managers and other experts in the ART industry in Australia and New Zealand, and 25 patient participants (Tables 1 and 2). The results are summarized in TABLE 3.

### Positive influences of commercialization

Most expert and patient participants saw the involvement of commercial providers in the delivery of ART as a necessity given broader healthcare priorities and the constraints of public funding. In addition, some participants (particularly in the expert group) were explicitly supportive of aspects of the private sector provision of ART, arguing that it enables the timely availability of ART treatments, and offers a variety of models with different pricing structures. Expert P20 and Patient C24 were among those who argued that flexibility and responsiveness is one of the benefits of commercialization:

> Expert P20: But what is offered potentially, I think perhaps better than the public system, is it is a far more efficient way of doing fertility services. There's not a waitlist to get in because the more cycles that are done, the more the company makes money. So if there's more cycles to be done, the company puts on more staff and makes more sessions available. It's just one of those things.

> Patient C24: So, if I was somebody who had to rely on public funding, I'd go on a waitlist, and I'd have no control over that. Whereas if I'm private, I can just phone them up and say, I want to do [IVF] . . . They're pretty full with appointments. You usually wait a month or so, but they'll fit you in. So you'll get in there sooner.

Some participants, for example, Expert P07, expressed the view that the involvement of commercial providers ensures high technical standards and evenness of quality and access across all Australian jurisdictions (at least in metropolitan areas):

> Expert P07: But I think we have a system that provides a very even quality of service across the country, and I am very proud of it and proud of having been part of it.

Others, such as Expert P18, spoke positively about the potential for clinical and technological innovation in the private sector:

> Expert P18: So I'm very much a believer that corporatization has led to an improvement in the possibilities for particularly technological advances, that something overseas that someone's produced — a new piece of equipment that improves success rates [for example] — the bigger companies can do it today.

The workforce specialization that is possible in the commercial sector was also seen as beneficial. Expert P09, for

**TABLE 1 DEMOGRAPHIC AND OCCUPATIONAL CHARACTERISTICS OF THE 31 ART INDUSTRY EXPERTS**

| Parameter | Value | | |
|---|---|---|---|
| | Total | Female | Male |
| Sex | 31 | 19 | 12 |
| Age (years), mean (range) | 54.4 (32–75) | 50.0 (32–66) | 62.1 (39–75) |
| **Main current role**[a] | | | |
| Patient advocate | 2 | 1 | 1 |
| Regulator | 2 | 1 | 1 |
| Manager | 5 | 2 | 3 |
| Fertility specialist | 11 | 6 | 5 |
| Nurse | 2 | 2 | 0 |
| Counsellor | 2 | 2 | 0 |
| Scientist | 3 | 2 | 1 |
| Embryologist and reproductive biologist | 2 | 2 | 0 |
| Referring general practitioner | 2 | 2 | 0 |
| **Sector of main current/most recent role if retired**[a] | | | |
| Public clinic | 0 | – | – |
| Commercial clinic – corporate chain – listed | 11 | – | – |
| Commercial clinic – corporate chain – privately held | 4 | – | – |
| Commercial clinic – standalone | 6 | – | – |
| Academia | 3 | – | – |
| Independent or other agency | 5 | – | – |
| General practice | 2 | – | – |
| **Country, state or territory of current/most recent role** | | | |
| New Zealand | 1 | – | – |
| Australia, nationwide role | 1 | – | – |
| New South Wales | 11 | – | – |
| Victoria | 9 | – | – |
| South Australia | 5 | – | – |
| Queensland | 3 | – | – |
| Western Australia | 1 | – | – |
| Australian Capital Territory | 0 | – | – |
| Northern Territory | 0 | – | – |
| Tasmania | 0 | – | – |
| **Practice setting** | | | |
| Urban | 25 | – | – |
| Mixed | 4 | – | – |
| Rural | 0 | – | – |
| Not stated | 1 | – | – |
| Not applicable | 1 | – | |

Data are *n* unless otherwise indicated.

[a] It was common for participants to occupy more than one role (e.g. clinician and manager) concurrently and many had had experience in a variety of roles, sectors and locations during their careers. As a result, they could bring a breadth of experience to their testimony.

ART, assisted reproductive technology.

example, valued the additional leadership and management roles it enables:

> Expert P09: [Large clinics] can also spread and invest more and people at the top – your scientific directors, nursing directors, things which smaller organizations or publicly funded organizations just can't afford. So those are benefits.

The governance structures in place in larger commercial organizations were also felt to promote efficiency and clinical quality and safety. Expert P08 was among those who saw the benefits of having robust governance systems and accountability to shareholders:

> Expert P08: I guess from a governance perspective. There's – if you're part of a larger organization, then there's an overarching governance system, which is probably a little more robust – robust might not be the correct word, a little more all-inclusive, I suppose, if you're reporting to shareholders, so from that governance perspective. Whereas if you're in a smaller unit, you don't have that requirement. So, I guess, the reports are somewhat more extensive if you have to report back to shareholders, and report back to a larger organization.

Some expert participants were optimistic about the potential of commercial players in the market to drive down costs through competition, although they acknowledged that this was yet to happen.

### Negative influences of commercialization

Both expert and patient participants expressed concerns about the effects of commercialization on the cost and quality of patient care. Some expert participants noted that the cost to both government and patients is steadily rising without commensurate improvements in the rate of live births. This was attributed in part to commercial forces, including clinics' responses to the incentives created by fee-for-service reimbursement. Patient C14 and Expert P02 were among those who spoke about the negative effects of incentives – in particular the perceived incentive to maximize the number of cycles conducted:

> Patient C14: Yeah, I think the incentive for clinics – there isn't an incentive for them to get women pregnant because if they get them pregnant the first time, then they're no longer a client, a customer. So the incentive, the whole process is incentivized for – well, as many rounds as possible.

> Expert P02: If you're running a private clinic where there's a stakeholder interest in increasing revenue, you want to increase the number of cycles that

**TABLE 2 DEMOGRAPHIC CHARACTERISTICS OF THE 25 ART PATIENT PARTICIPANTS**

| Parameter | Value |
|---|---|
| **Age (years)**[a] | |
| Mean | 37 |
| Range | 26–50 |
| **Setting** | |
| Metropolitan | 13 |
| Rural and regional | 12 |
| **Family structure** | |
| Single | 9 |
| Same-sex couple | 4 |
| Mixed-sex couple | 12 |
| **Countries, states or territories represented in the sample** | |
| New Zealand | 1 |
| New South Wales | 6 |
| Victoria | 11 |
| Queensland | 2 |
| South Australia | – |
| Tasmania | 4 |
| Western Australia | 1 |
| Northern Territory | – |
| Australian Capital Territory | – |
| **Occupational categories represented in the sample**[b] | |
| Education | 2 |
| Policy and research | 5 |
| Law | 1 |
| Insurance | 1 |
| Public service | 1 |
| Administration | 2 |
| Allied health, public health and health sciences | 4 |
| Medical | 5 |

Data are *n* unless otherwise indicated.
[a] For five participants age was not stated.
[b] For four participants occupation was not stated.
ART, assisted reproductive technology.

> you do, whether it's the same person or different people, it doesn't matter.

More specifically, concern was expressed about the use of IVF rather than less invasive interventions, and the increasing use of 'add-ons'. Expert P16 was among the participants who expressed concern about the tendency to adopt add-ons before their effectiveness has been demonstrated and the subsequent difficulty in reversing perceptions:

> Expert P16: My observation is there's often rapid adoption of adjuvants … So I've lost count of the number of panaceas that have been 'everyone has to have it' for 18 months, and all of a sudden, it's like, 'Shush, let's not talk about that dodgy shit any more', because the evidence isn't supporting it.

Patient participants, such as Patient C09, often raised concerns about the cost of add-ons, particularly for those with financial stresses:

> Patient C09: So he was always trialling new things or experimenting. So I found absolutely every single cycle was different with medications and trying different things, new things … And you know, you're talking about injections that are $100, $200, $300, $400 each … Yeah, if you were on a really tight budget or – well I mean the majority of people are, you know. That probably would have been quite a stress.

Many participants, for example, Expert P29, expressed the concern that out-of-pocket costs and other commercial decisions (for example, closure of clinics in regional areas) accentuate inequities in access:

> Expert P29: Until Australia across the board adopts more equality, IVF is, I hate to say this but it is, assisted reproductive technology is for relatively wealthy people in Australia I think.

Many participants also expressed the view that commercial imperatives may lead to care that is excessively protocolized, whereby each patient is given the same care irrespective of their wishes or needs, with negative impacts on patient–provider relationships, patient-centred care and continuity of care. As Patient C22 observed, this can make patients feel that they do not count as individuals, but are rather seen as 'numbers':

> Patient C22: I feel like in clinics you can end up feeling like a number to someone rather than an actual human being. I think a lot of them lose perspective that on the other end of this blood test there is actually a person who has feelings and emotions.

As Expert P08 argued, excessive protocolization can have clinical consequences such as repeating practices that have not worked:

> Expert P08: So I think sometimes the bigger the clinic, the more difficult it is to maintain that close relationship with the patient … I think the main difference is individualized care. So it's about not – and it's about that review of patients. So it's about looking at those patients. I mean, you often hear patients who'll say, 'I've had seven cycles' and no cycle has ever been changed then they just keep repeating, repeating, repeating the same cycles. And so, there's no one looking because

**TABLE 3 SUMMARY OF RESULTS FROM ART INDUSTRY EXPERT AND PATIENT INTERVIEWS**

| Broad domain | Positive influences of commercialization | Negative influences of commercialization |
|---|---|---|
| Patient experience | Greater availability of services<br>Choice of services and pricing models | Cost to patients<br>Inadequate informed consent<br>Complex fee structures and schedules<br>Insufficient personalization of care<br>Misleading marketing and advertising |
| Clinical practice | Technical quality of care<br>Consistency of standards | Incentivization of IVF cycles<br>Excessive use of interventions that lack sufficient evidence to be considered part of standard care |
| Organizational | Efficiency and responsiveness of organizational governance<br>Clinical and technological innovation<br>Workforce specialization | Less-qualified staff in patient-facing roles<br>Regulatory system not well suited to commercial environments |

> contact with doctors is not — you don't necessarily go back and see your doctor an awful lot.

Some participants, for example Expert P08, claimed that commercial imperatives also affect the number and seniority of the staff employed in patient care positions, and that this may affect the quality of care:

> Expert P08: They outsourced and they brought in one or two junior inexperienced counsellors who they could pay a lot less money to . . . I think their rates of pay were too high and they decided that it's better to use younger staff to save money.

For some participants, commercial imperatives were associated with inadequate consent and transparency about treatments and their costs. As Experts P20 and P14 argued, this can have a range of negative impacts such as overprescribing add-ons and unexpected costs:

> Expert P20: I'm sure there are doctors and things out there who overprescribe things without giving properly fully informed consent about adjuvants. I don't think that's — I think that would be quite common.

> Expert P14: It's not a level playing field. There's information imbalance in terms of the information that's held by the clinic and the people that provide the treatment and the patients. And information about costs is not transparent. You can't compare one clinic with another. Patients tell us that they start off thinking they're going to be up for one set of costs and they get halfway through treatment and they find out there's all these extras that are going to cost them more.

Patients reported that clinics' marketing claims make decision-making even more difficult. Patient C02 was among those who were critical of marketing practices, in particular because of their impacts on 'vulnerable' people:

> Patient C02: I don't think any of these big listed companies should be advertising because, at the end of the day, they're advertising because they want more money for their shareholders, and I think it's wrong . . . And you're preying on very vulnerable people, you know. I think everybody that turns up wanting to have a baby through IVF is a vulnerable person at the time — some more vulnerable than others.

A number of patient and expert participants expressed the view that Australia's regulatory system has not kept pace with the commercialization of ART and now lacks sufficient authority and power to protect patients. For example, as Expert P15 claimed, competition can be an obstacle to the disclosure of adverse events:

> Expert P15: I guess the self-regulatory part of it . . . works to an extent. I think there are some weaknesses there in terms of adverse event reporting, for example. You're basically reporting yourself to a potential competitor — [and] the information is shared widely among the boards.

In this regard, patient participants highlighted the limitations of regulation of marketing and advertising:

> Patient C13: There is no regulation in Australia preventing the BS in marketing that is pushed on women, that ultimately is actually leading to a woman never having babies.

### The need for reform in the governance and funding of ART

Participants' suggestions for reform reflected their experiences and views of problems with the system. This quote from Patient C13 encapsulates ideas about the objectives of reform that were shared widely by expert and patient participants, including that there should be greater transparency, greater regulatory independence and different incentive structures:

> Patient C13: We need to come up with a solution that involves the fertility sector having the primary focus, and only focus, on getting women pregnant as quickly and as cheaply as possible and that's not the focus right now. We need transparency about success by clinics. Stop hiding the names of these clinics. We need to incentivize success, not finances. And we need a strong public sector, we need proper regulation. They're probably the three things — transparency, public sector, independent regulation.

Some expert participants were satisfied with ART regulation as it stands, but a significant majority, and many of the patients, advocated greater regulatory oversight. As Patient C02 noted, the vulnerability of ART patients is a factor in calls for greater regulation:

> Patient C02: They definitely need to be regulated a lot more. They are taking advantage of vulnerable people.

There were differing views on whether the additional oversight ought to be internal or external, with some participants, for example Patient C13, arguing for independence (because of failures of internal regulation) and others, for example, Expert P20, in favour of more self-regulation (because of the negative impacts on the sector of external regulation):

> Patient C13: Well, I think first and foremost, [improvement would mean] having independent regulation so that the sector is not self-regulating. A regulator that only permits the use of proven evidence-based technology, and that, if they are doing an experimental treatment, that it is clearly identified to the patient that it's experimental.

> Expert P20: We don't want to over-regulate the industry but I think that, unless we do a little bit more self-regulation, then outside regulation could be imposed upon it and I think that would be a disaster. So I think my solution would be yes, you create some more in-house regulation.

Participants advocated reform particularly with regard to pricing, informed financial consent, and advertising and other forms of marketing. Expert P14 argued for expansion of the criteria in the Reproductive Technology Accreditation Committee (RTAC) code of practice to include, for example, guidance on add-ons and costs:

> Expert P14: Well, there's a code of practice and there could be criteria within the code of practice that clinics need to adhere to. Just like the advertising guidance around success rates, there could be some advertising guidance around add-ons and adjuvants that could be added … It's not just about success rates. It's also about costs. And it's very difficult for patients to decipher information on costs as well. So there could be technical bulletins produced in relation to presentation of costs for patients.

Some participants argued for greater national uniformity in regulation. As Expert P20 explained, differences between jurisdictions can cause confusion and inefficiency:

> Expert P20: I think it's probably better to have one regulatory unit that's the same across the country. I think it creates a confusion for clinics, extra work for clinics and confusion for patients. So I'd be more of an advocate of having one regulatory system nationwide.

There were also calls for changes to the funding of ART, in each case motivated by concerns about equity, transparency, value for money and/or limiting patient exposure to unnecessary costs and interventions. Suggestions aimed at increasing access to lower-cost services included boosting the number of publicly funded and independent services in the system, and obliging all clinics to provide a certain number or proportion of public cycles to patients with low means, along the lines of the model operating in New Zealand:

> Expert P28: We know that the New Zealand funding model has a public component to it and, in fact, they're obliged to fund or treat so many patients through the public system, with a criteria of eligibility. I think from an equity perspective it would be nice to see something like that come in, where the door is open to everyone to seek this sort of treatment, not just for the people who can afford it.

Suggestions aimed at improving the quality and consistency of care included limiting Medicare subsidies to clinics that adhere to guidelines and perform evidence-based interventions, and increasing public funding for fertility investigations and non-invasive treatments. Many participants, for example Expert P17, recommended limiting the number of publicly subsidised cycles women may access (although many others criticized such a move on clinical or justice grounds):

> Expert P17: How do you maximize success for the patients undergoing IVF? That's the end point. So it might be limiting the numbers, limiting the age, investigating them thoroughly before they embark upon their first IVF cycle.

## DISCUSSION

The study's results suggest that, while patients and providers of ART see some benefits in the current system, in which ART is provided largely in the private sector, many also see the need for critical examination of the industry and for regulatory reform. This is consistent with views expressed in Australian government reviews and inquiries, which have called for regulatory review of the sector aimed at improving the patient experience, the quality and safety of services, consent and information-giving processes and standards, and inclusivity and access (*Allan, 2017*; *Gorton, 2019*; *Health Care Complaints Commissioner Victoria, 2020*). In the UK there have been calls for regulatory reform focused on similar areas (*Chain, 2022*).

While it is beyond the scope of this paper to ascertain the veracity of concerns or make specific recommendations, some reflections can be offered on ways the problems and suggestions identified here might be addressed by those seeking to safeguard patient welfare in the context of commercialized medicine.

The ART industry in Australia is currently subject to both professional self-regulation and external regulation. For example, the accreditation of ART clinics is an example of self-regulation. This is the responsibility of the RTAC, established by the FSANZ. The RTAC aims to ensure that ART clinics comply with government laws and guidelines, including those of the National Health and Medical Research Council. Health professionals are also externally regulated by statutory bodies such as the Australian Health Practitioner Regulation Agency and its National Boards. The results of this study suggest that there may be a benefit in reviewing the current system to identify strengths and deficiencies, particularly with regard to the management of commercial influences on ART.

It will be important to think carefully about whether the types of problem that have been identified (if subsequently confirmed) require regulation, and if so, whether this should be external or internal (*Epstein, 2018*; *Frith, 2018*; *Wilkinson et al., 2019*). External or independent regulation has the advantage of being 'public', enforceable and reflective of broad societal norms and standards. But it may come with costs — potentially constraining the market (and along with it the flow of benefits associated with well-functioning markets, such as reduced cost to patients and enhanced access) and slowing down innovation

(*Lipworth et al., 2021*). External regulation may also be costly to the taxpayer, bureaucratic, slow to respond to evidence of wrongdoing, and driven by political imperatives.

Internal regulation — or self-regulation — has the advantage of being nuanced, adaptable and appealing to health professionals, but it may be insufficient to overcome unconscious biases and strong commercial imperatives (*Frith, 2018*; *Mayes et al., 2016*; *Walsh, 2018*). Recent events in the cosmetic surgery industry have revealed both how internal regulation may be inadequate to control the behaviour of practitioners and how external regulation can be slow to respond to problems when they emerge (*Australian Associated Press, 2022*).

To be effective, both external and internal regulation need to be supported by other mechanisms, such as consumer-facing information sources (e.g. the YourIVFSuccess website), professional codes of ethics (*Mayes et al., 2016*; *Walsh, 2018*) and governance processes. Importantly, these codes of ethics and governance processes (such as clinical ethics committees) need to more directly and rigorously address commercial influences. While there are already codes of ethics for ART, and many clinics have governance processes in place (including clinical ethics committees), these do not typically systematically address the management of commercial influences.

Ethics programmes that focus on the ethical features and behaviours of organizations (rather than broad health systems or individuals) may also be helpful to providers seeking to address the challenges that arise from their obligations to shareholders and patients and to the many different stakeholders who have legitimate interests in their outcomes. In this regard, there may be lessons to learn from organizational ethics programmes, which encourage organizations to examine how their aims and values can be expressed ethically through their governance structures, policies and practices (*Frith, 2018*). These frameworks are particularly suited to settings like ART, where organizational and clinical ethics are closely intertwined (*Bean, 2011*).

'Critical organizational ethics' has been recently conceptualized as a variation of the approach for the ART context (*Frith, 2018*). Bringing together 'critical' social science and bioethics, it extends both organizational and clinical ethics so that management and clinicians can understand and respond to the social context and power structures in which they operate. It emphasizes the importance of including the voices of staff, patients, service users and members of the public in the design, delivery and evaluation of healthcare services — areas where the current findings suggest there is room for improvement. Such programmes, if implemented by ART providers and subjected to ongoing evaluation, could potentially harness the strengths of a highly commercialized industry, and deliver commercial benefits by making responses to community needs and wants explicit and showing both patients and staff that their concerns are taken seriously.

It is beyond the scope of this article to consider the implications of the participants' suggestions relating to broader issues of system funding. These decisions are complex and depend on the degree to which society values goods such as genetic and gestational parentage and how these are positioned relative to other uses of limited resources. It is, however, likely that greater attention to the ways in which funds are being used will assuage some concerns about the current funding system.

As with all qualitative research, the authors cannot claim that their findings are generalizable beyond the sample. The study might also have been impacted by selection bias, with either critics or defenders of the industry being more enthusiastic to express their views. Nevertheless, the diverse research team (including ART specialists, ethicists, lawyers and social scientists), the sample size (which is large for a qualitative study of this nature), the inclusion of patients, clinicians and other industry representatives and explicit attention to both the positive and negative aspects of commercialization make it likely that the findings of the current study have captured the key perspectives of all relevant stakeholders.

## CONCLUSIONS

The participants recognized the benefits of commercial investment in healthcare, particularly with regard to sustainability, consistency and patient choice. They also considered commercial forces to have a number of negative impacts, including increased costs to government and patients, excessive use of interventions that lack evidence of effectiveness, inadequately informed clinical and financial consent, and diminished patient-centred care. Many considered that regulatory reforms, as well as organizational cultural initiatives, are needed as means to ensure the primacy of patient well-being. The views expressed in this study should be systematically and critically examined to derive insights into how best to govern ART.

While this research has focused on commercial influences on ART, and might therefore reflect some idiosyncrasies of this area of practice, there are similar developments in other medical specialties, such as medical imaging, gastroenterology, pathology, dermatology and general practice (*Busam and Shah, 2023*; *Gleicher et al., 2019*; *Patrizio et al., 2022*). The current findings and recommendations therefore have the potential to be more broadly applied and could provide both an impetus and a conceptual framework for integrating governance initiatives across clinical settings.

## DATA AVAILABILITY

The data that has been used is confidential.

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## SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.rbmo.2024.103850.

## REFERENCES


Allan, S., 2017. Report on the review of the Assisted Reproductive Treatment Act 1988 (SA) [WWW Document]. Trove. URL https://nla.gov.au/nla.obj-415529282 (accessed 10.7.22).

Alonso, A., Deans, R., Nesbitt-Hawes, E., Yazdani, A., McCormack, L., Koh, Y.Y., Abbott, J., 2021. Gynaecological and IVF procedures billed through the Medicare Benefits Schedule (MBS) during the COVID-19 pandemic. Australian and New Zealand Journal of Obstetrics and Gynaecology 61, 585–590 . https://doi.org/10.1111/ajo.13355.

Australian Associated Press, 2022. 'Irresponsible': regulator accused of not doing enough to protect patients in cosmetic surgery reform [WWW Document]. The Guardian Australia. URL https://www.theguardian.com/australia-news/2022/sep/01/cosmetic-surgery-in-australia-to-be-monitored-by-enforcement-unit-to-improve-patient-safety (accessed 11.22.22).

Australian Competition and Consumer Commission (ACCC), 2016. IVF "success rate" claims under the microscope [WWW Document]. URL https://www.accc.gov.au/media-release/ivf-success-rate-claims-under-the-microscope

Australian Government Department of Health, 2020. Medicare Benefits Schedule Review Taskforce: Taskforce Report on Gynaecology MBS Items. Australian Government Department of Health, Canberra.

Bean, S., 2011. Navigating the Murky Intersection between Clinical and Organizational Ethics: A hybrid case taxonomy. Bioethics 25, 320–325. https://doi.org/10.1111/j.1467-8519.2009.01783.x.

Blakely, B., Williams, J., Mayes, C., Kerridge, I., Lipworth, W., 2019. Conflicts of interest in Australia's IVF industry: an empirical analysis and call for action. Human Fertility 22, 230–237. https://doi.org/10.1080/14647273.2017.1390266.

Borsa, A., Bejarano, G., Ellen, M., Bruch, J.D., 2023. Evaluating trends in private equity ownership and impacts on health outcomes, costs, and quality: systematic review. BMJ 382, e075244. https://doi.org/10.1136/bmj-2023-075244.

Braun, V., Clarke, V., Hayfield, N., Terry, G., 2019. Thematic Analysis. In: Liamputtong, P. (Ed.), Handbook of Research Methods in Health Social Sciences. Springer Singapore, Singapore, pp. 843–860. https://doi.org/10.1007/978-981-10-5251-4_103.

Bruch, J.D., Borsa, A., Song, Z., Richardson, S.S., 2020. Expansion of Private Equity Involvement in Women's Health Care. JAMA Internal Medicine 180, 1542–1545. https://doi.org/10.1001/jamainternmed.2020.3567.

Busam, J.A., Shah, E.D., 2023. The Rise of Private Equity in Gastroenterology Practices. Gastroenterology & Hepatology 19.

Chain, J., 2022. The HFEA 30 years on — what needs to change? [WWW Document]. Human Fertilisation and Embryology Authority. URL https://www.hfea.gov.uk/about-us/news-and-press-releases/2022-news-and-press-releases/fertility-2022-julia-chain-chair-of-the-hfea/ (accessed 9.27.23).

Chambers, G.M., Dyer, S., Zegers-Hochschild, F., de Mouzon, J., Ishihara, O., Banker, M., Mansour, R., Kupka, M.S., Adamson, G.D., 2021. International Committee for Monitoring Assisted Reproductive Technologies world report: assisted reproductive technology, 2014. Human Reproduction 36, 2921–2934. https://doi.org/10.1093/humrep/deab198.

Epstein, M, 2018. The corruption of medical morality under advanced capitalism, in: Therese Feiler, Joshua Hordern, Andrew Papanikitas (Ed.), Marketisation, Ethics and Healthcare: Policy, Practice and Moral Formation.

Farquhar, C., Vercellini, P., Marjoribanks, J., 2017. Gynaecologists and industry: ain't no sunshine. Human Reproduction 32, 1543–1548. https://doi.org/10.1093/humrep/dex228.

Fertility Society of Australia and New Zealand, 2021. Code of practice for assisted reproductive technology units.

Frith, L., 2018. A solution to the challenges of markets in healthcare? In: Feiler, Therese, Hordern, Joshua, Papanikitas, Andrew (Eds.), Marketisation, Ethics and Healthcare: Policy, Practice and Moral Formation. Routledge, p. 16.

Gleicher, N., Kushnir, V.A., Barad, D.H., 2019. Worldwide decline of IVF birth rates and its probable causes. Human Reproduction Open 2019, 1–7. https://doi.org/10.1093/hropen/hoz017.

Gorton, M., 2019. Helping Victorians create families with assisted reproductive treatments. Final report of the Independent Review of Assisted Reproductive Treatment. Victorian Government, Melbourne.

Health Care Complaints Commissioner Victoria, 2020. Inquiry into assisted reproductive treatment practices in Victoria. Victoria.

Heneghan, C., Spencer, E.A., Bobrovitz, N., Collins, D.R.J., Nunan, D., Plüddemann, A., Gbinigie, O., Onakpoya, I., O'Sullivan, J., Rollinson, A., Tompson, A., Goldacre, B., Mahtani, K.R., 2016. Lack of evidence for interventions offered in UK fertility centres. BMJ i6295. https://doi.org/10.1136/bmj.i6295.

IBISWorld, 2023. Fertility Clinics in Australia - Market Size, Industry Analysis, Trends and Forecasts (2023-2028)| [WWW Document]. URL https://www.ibisworld.com/default.aspx (accessed 9.25.23).

Jeve, Y.B., Potdar, N., Blower, J.A., Gelbaya, T., 2018. Strategies to improve fertilisation rates with assisted conception: a systematic review. Hum Fertil (Camb) 21, 229–247. https://doi.org/10.1080/14647273.2017.1324182.

Lensen, S., Chen, S., Goodman, L., Rombauts, L., Farquhar, C., Hammarberg, K., 2021. IVF add-ons in Australia and New Zealand: A systematic assessment of IVF clinic websites. Australian and New Zealand Journal of Obstetrics and Gynaecology 61, 430–438. https://doi.org/10.1111/ajo.13321.

Lipworth, W., Wiersma, M., Ghinea, N., Hendl, T., Kerridge, I., Lysaght, T., Munsie, M., Rudge, C., Stewart, C., Waldby, C., 2021. The Oversight of Clinical Innovation in a Medical Marketplace. In: Laurie, G., Dove, E., Ganguli-Mitra, A., McMillan, C., Postan, E., Sethi, N., Sorbie, A. (Eds.), The Cambridge Handbook of Health Research Regulation. Cambridge University Press, pp. 287–295. https://doi.org/10.1017/9781108620024.036.

Mayes, C., Blakely, B., Kerridge, I., Komesaroff, P., Olver, I., Lipworth, W., 2016. On the fragility of medical virtue in a neoliberal context: the case of commercial conflicts of interest in reproductive medicine. Theoretical Medicine and Bioethics 37, 97–111. https://doi.org/10.1007/s11017-016-9353-0.

National Health and Medical Research Council, 2017. Ethical guidelines on the use of assisted reproductive technology in clinical practice and research. National Health and Medical Research Council, Canberra.

Patrizio, P., Albertini, D.F., Gleicher, N., Caplan, A., 2022. The changing world of IVF: the pros and cons of new business models offering assisted reproductive technologies. J Assist Reprod Genet. https://doi.org/10.1007/s10815-022-02399-y.

Van De Wiel, L., 2020. The speculative turn in IVF: egg freezing and the financialization of fertility. New Genetics and Society 39, 306–326. https://doi.org/10.1080/14636778.2019.1709430.

Walsh, 2018. Commercialisation and the corrosion of the ideals of medical professionals. In: Feiler, Therese, Hordern, Joshua, Papanikitas, Andrew (Eds.), Marketisation, Ethics and Healthcare: Policy, Practice and Moral Formation. Routledge, pp. 133–146. https://doi.org/10.4324/9781315186351-9.

Wilkinson, J., Malpas, P., Hammarberg, K., Mahoney Tsigdinos, P., Lensen, S., Jackson, E., Harper, J., Mol, B.W., 2019. Do à la carte menus serve infertility patients? The ethics and regulation of in vitro fertility add-ons. Fertility and Sterility 112, 973–977. https://doi.org/10.1016/j.fertnstert.2019.09.028.


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