Australian Government
Department of Health

Submission to the Senate Standing Committee on Community Affairs: Australian Institute of Health and Welfare Amendment (Assisted Reproductive Treatment Statistics) Bill 2019

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1. INTRODUCTION

The Department of Health welcomes the opportunity to provide a submission to the Senate Standing Committee on Community Affairs on the 'Australian Institute of Health and Welfare Amendment (Assisted Reproductive Treatment Statistics) Bill 2019' (the ART Bill).

In summary, the Department's submission outlines:

- in principle support for the publication of performance information at the unit level, including in relation to accredited Assisted Reproductive Technology (ART) Units;[1]
- the need for a cautious approach to public performance reporting, including stakeholder consultation and consideration of potential sensitivities and risks; and
- the Australian and New Zealand Assisted Reproduction Database (ANZARD) is well placed to provide public performance reporting at the accredited ART Unit level.

2. AUSTRALIAN GOVERNMENT ROLE

The Australian Government supports facilities with ART via the provision of funding and the development of the national women's and men's health policies, which address reproductive health.

ART Funding

Medicare Benefits Schedule (MBS)

The MBS includes ART services that provide Medicare rebates for complete ART cycles for patients where it is deemed clinically relevant. In 2018-19, 285,558 ART services were claimed and Medicare paid a total of **$256.6 million** in benefits for these services. (Refer to Attachment A for more information). Patients must be undertaking ART treatment under the relevant MBS item to access Pharmaceutical Benefits Scheme (PBS) subsidised medicines.

In Vitro Fertilisation (IVF) Program

The Australian Government provides PBS subsidised fertility medicines for Australian women, via the In Vitro Fertilisation (IVF) Program. Expenditure on the Program was approximately **$112 million** in the 2018 calendar year.

National women's and men's health policies

The *National Women's Health Strategy* 2020-2030 outlines a national approach to improving health outcomes for Australian women and girls. Maternal, sexual and reproductive health is a priority, aiming to increase access to health care information, diagnosis, treatment and services in this area, including a commitment to improve equitable access to evidence-based IVF. Click here for more information.

The *National Men's Health Strategy* 2020-2030 supports men and boys in Australia to live a long, fulfilling and healthy life. Sexual and reproductive health is a priority. It recognises that male reproductive health conditions, including infertility, are common and suggests that preconception health promotion, fertility and reproductive health issues warrant increased attention across primary care. Click here for more information.

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[1] ART Units are accredited by the Australian Fertility Society's (AFS) Reproductive Technology Accreditation Committee (RTAC). RTAC grants licences to practice ART in Australia. The AFS is the peak body representing scientists, doctors, researchers, nurses, consumers and counsellors in reproductive medicine in Australia and New Zealand https://www.fertilitysociety.com.au/home/about/

3. PUBLIC REPORTING ON HEALTH CARE OUTCOMES

The Department supports, in principle, the move towards greater health service transparency and accountability through public reporting of outcomes data, including in relation to accredited ART Units.

The Hon Greg Hunt MP, Minister for Health, recently wrote to the IVF Directors' Group expressing his commitment to working with IVF Directors and their colleagues in the coming months to reach agreement on how greater transparency and access to data on success rates can be achieved.

Public reporting can realise significant benefits for a range of stakeholders, including:

- accelerating improvements in the safety and quality of clinical practice and patient outcomes. For example, in 2006, Sweden's Acute Coronary Care Registry published data on how well Swedish hospitals complied with national clinical guidelines and on their patient survival rates. This was followed by an improvement of 40 per cent in quality scores of poorer performers and an overall rate of improvement for all hospitals of 22 per cent in the following two years;
- providing consumers with information to support health care decision making and choice;
- informing health service, policy, regulatory and funding decisions; and
- contributing to the sustainability of public and private health care systems.

Internationally, public reporting on the quality of health care plays a key role in countries such as the UK, US, Sweden and NZ. In Australia, a number of public reporting related initiatives are underway, including the:

- Australian Health Performance Framework (AHPF), which aims to provide a single, flexible vehicle to support system-wide reporting on Australia's health and health system performance. The Australian Institute of Health and Welfare is developing a 'National Front Door' website for public reporting of AHPF indicators, which will be launched in December 2019. The AHPF supersedes existing national health reporting frameworks.

- Draft National Clinical Quality Registry Strategy, which seeks to drive improvements in the quality and value of health care to achieve better health outcomes for all Australians. The creation of an environment that supports the provision of tailored clinical quality registry (CQR) performance information to a range of stakeholders, including consumers, is a key Strategy objective. Such an environment would: be developed in partnership with key stakeholders; protect patient privacy, focus on supporting clinicians to improve their clinical practice; and involve quality assured, national CQRs with robust data governance arrangements. Click here for more information.
    - The high performing Australian and New Zealand Hip Fracture Registry (ANZHFR) began public reporting of identified hospital level data in its 2018 Annual Report.[2] This included Australian hospitals that consented to identification (83 per cent of hospitals) and all New Zealand hospitals entering patient level data. ANZHFR collects, analyses, and provides feedback and reports on data provided by Australian and New Zealand hospitals on the clinical care and patient

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[2] https://anzhfr.org/wp-content/uploads/2018/11/2018-ANZHFR-Annual-Report-FULL-FINAL.pdf

outcomes of people, aged 50 years and over, admitted to hospital due to hip fracture.

As recognised by the draft National CQR Strategy, there are important precursors to the introduction of public reporting, including the need for stakeholder consultation and the need to identify and address potential issues and risks related to public reporting.

4. POTENTIAL SENSITIVITIES AND RISKS

Public reporting of health care outcomes that identifies providers at the clinician or hospital/unit/clinic level is a sensitive issue in Australia. During the 2019 consultation on the draft National CQR Strategy, some clinicians and peak bodies raised concerns about a focus on ‘league tables’ and ‘naming and shaming’ clinicians, rather than on quality improvement. Other issues included the importance of: quality data; accurate risk adjustment of data; and correct reporting and interpretation of data, including by consumers and the media.

Public reporting of ART outcomes in the US and UK

The United States Society for Assisted Reproductive Technology Clinical Outcomes Reporting System and the United Kingdom Human Fertilisation and Embryology Authority are large registries that publicly report ART outcomes at the national and clinic/unit level.

Chambers et al (2019) note that positive impacts of this reporting include outcome transparency and better informed consumers.[3]

However, they also outline unintended consequences and issues relating to ART public reporting, including the potential for it to adversely impact clinical practice, rather than improve it. For example, a change of clinician focus from effective, safe and equitable treatment to achieving higher success rates may lead to:[4]

- selective treatment of women where ART Units may prefer to treat only those women with a higher likelihood of success. (Note the National Women’s Health Strategy includes commitment to improve equitable access to evidence-based IVF).
- implantation of multiple embryos, as Chambers et al (2019) explain:[5]

  > *… pregnancy or live birth rates as measures of success alone can incentivize… the transfer of more than one embryo to improve pregnancy and live birth rates at the expense of a higher multiple birth rate (which increases the risk of adverse health outcomes for mother and infant)… The most significant safety challenge associated with ART treatment is the risk of multiple gestation pregnancy...*

  - In 2015, the Australian and New Zealand multiple birth rate relating to ART was 4.4 per cent compared to 35.3 per cent in the US.

Other issues include:[6]

- the lack of consistent approaches, internationally, to measuring, risk adjusting, analysing, and reporting outcomes, which hinders effective comparisons;
- the inadequacy of simplistic approaches to reporting highly complex ART outcome data;

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[3] Chambers GM, Doody K & Crawford S (2019) ‘Reporting ART Success Rates’ in ‘Assisted reproductive technology surveillance’. Ed. Kissin DM, Adamson GD, Chambers GM, De Geyter C. Cambridge, United Kingdom: Cambridge University Press (2019). ISBN 978-1-108-49858-6 (Hardback and online)

[4] Ibid

[5] Ibid p39

[6] Ibid

- the need for reported outcome measures that are easily understood and meaningful for consumers.

5. THE ART BILL

The ART Bill proposes that an ART centre (Unit) must report, for a financial year: the number of women given ART by the centre and their age; the types of ART and the number of times each type of ART was given by the centre; the number of pregnancies and number of live births reasonably attributable to ART given by the centre; and any other statistical information specified in the regulations that relates to ART given by the centre.

We note that the ART Bill does not provide detailed information on the process or the complete data set to be collected and reported, and there is potential for:

- significant duplication, inefficiency and errors related to the collection of data already collected, analysed and reported by ANZARD, in a comprehensive and meaningful manner; and
- a narrow focus on rates of pregnancy and live births, which could have an adverse impact on clinical practice and the women and babies involved.

6. AUSTRALIAN AND NEW ZEALAND ASSISTED REPRODUCTION DATABASE

ANZARD is a CQR that monitors perinatal outcomes of assisted reproduction and assesses the effectiveness of assisted reproductive therapies. Established in 2002, it is operated by the independent National Perinatal Epidemiology and Statistics Unit of the University of NSW.

ANZARD is the most complete In-Vitro Fertilisation (IVF) database in the world, with 100 per cent coverage of all ART cycles in Australia (note that accredited ART Units must report their data to ANZARD to claim MBS items). ANZARD includes a comprehensive set of prognostic factors associated with IVF, required to interpret and present meaningful success rates (for example, age, period of infertility, number of previous failed cycles, number of cycles, donor or no donor).

ANZARD drives improvements in the safety and quality of ART clinical practice and patient outcomes through the provision of risk adjusted, benchmarked feedback to accredited ART Units on their performance. Units that have performance issues are then assisted to improve their clinical practice. Trust and confidence in ANZARD is essential for clinician engagement in quality improvement activities.

Public reporting website

ANZARD has developed a proposal to build a website for the public reporting of accredited ART Unit outcomes, with the support of the Fertility Society of Australia. As above, ANZARD includes a comprehensive set of prognostic factors associated with IVF, required to interpret and present meaningful success rates. This would help reduce the potential adverse impact of a narrow focus on pregnancy and live birth rates, currently included in the ART Bill. Its development would be informed by consultation and testing with clinicians and consumers on meaningful, consumer friendly content. The website would be designed to encourage joint patient-clinician decision making and minimise the potential for adverse impacts on clinical practice, outlined above.

Online IVF Patient Predictor

ANZARD has developed a proposal to build a publicly accessible ‘Online IVF Patient Predictor’, based on their entire database. The predictor would enable consumers to enter their personal prognostic indicators (including male data) and receive a personalised, estimated, average chance of having a live birth with ART. The development of the predictor tool would include extensive testing with consumers. Results would be easy to understand and provided with a warning that results are based on averages and therefore should be discussed with their clinician.

Performance reporting website and the Online IVF Predictor

The use of the same database for accredited ART Unit public performance reporting and the online predictor tool would provide complementary information to assist consumers to make informed choices about, for example, whether to proceed with ART and which accredited ART Unit to attend.

MBS Review Taskforce Gynaecology Clinical Committee review of MBS ART services

In December 2018, the MBS Review Taskforce (Taskforce) considered that the Government be allowed to freely access the current compulsory dataset supplied by providers to ANZARD to facilitate work on initiatives designed to make complex ART outcome data more understandable and informative for consumers.

The Taskforce’s draft recommended initiatives, published for public consultation, included the development of a publicly accessible ‘ART success calculator’ that allows patients to anonymously provide personal prognostic indicators and receive a personalised estimate of their likely live delivery rate with ART treatment. (As outlined above, ANZARD has developed a proposal for an ‘Online IVF Patient Predictor’.) The Taskforce considered its advice on these issues at their meeting on 13-14 August 2019. The Taskforce will finalise its advice to Government by the end of 2019.

7. CONCLUSION

In conclusion, the Department considers that ANZARD, a high quality CQR, is well placed to deliver public reporting on accredited ART Unit performance. ANZARD has already developed proposals to build a public reporting website and an online predictor tool, based on data it already collects, analyses and feeds back to Accredited ART Units. It has identified and addressed the issues and risks involved and has the capacity to provide comprehensive, meaningful, consumer friendly public reporting, with the support of the Fertility Society of Australia.