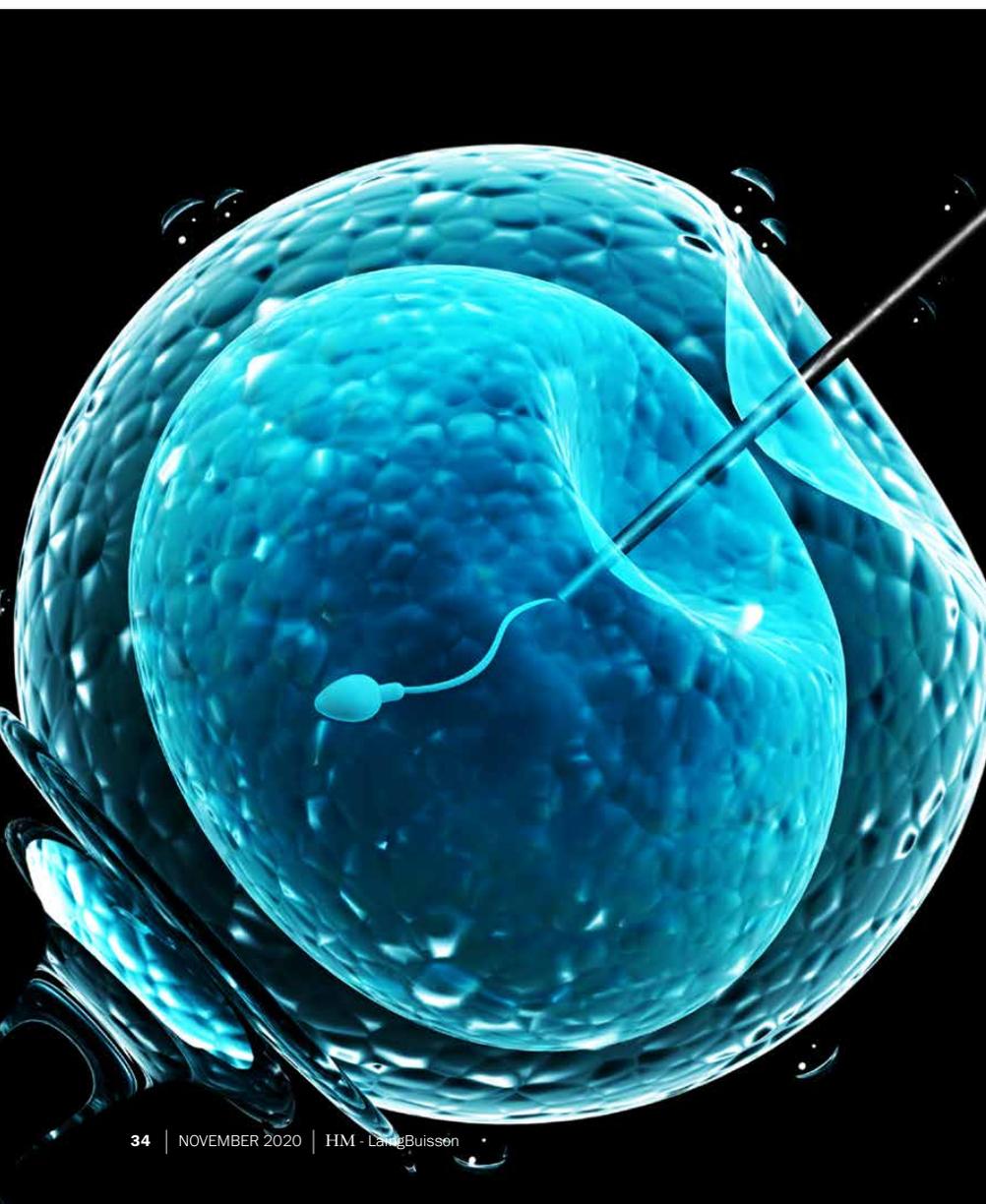


The patchwork of regulation governing IVF treatment in Europe could be seen as a significant barrier to IVF providers looking to build pan-European brands, but these same variations are also driving a surge in cross-border treatment. Candesic partner, **Marc Kitten**, and analyst, **Dr Nigel De Melo**, discuss how consolidation in what remains a fragmented market could help drive safer and more accessible IVF services



Birth beyond borders

how consolidation can drive better outcomes in IVF



The birth of the world's first in vitro fertilisation (IVF) baby, in 1978, was a landmark moment that marked the first key step for IVF treatments in combating infertility. The following two years saw the foundation of the first IVF clinic in the UK, pioneering the way for both large public hospitals and specialised private players to establish their own clinics.

The rise in commercial use of infertility treatments and the fractured, dispersed nature of IVF firms and clinics lead to the consolidation of practices at a national level.

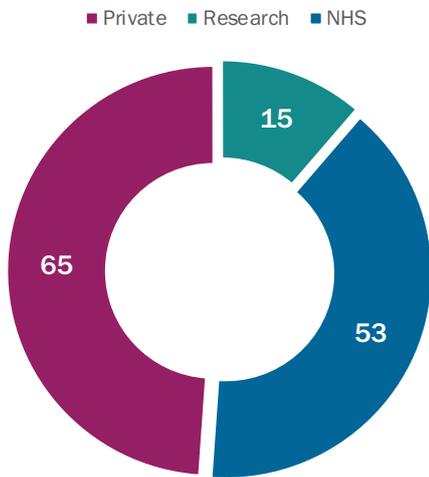
Today, several private players attempt to continue their consolidation efforts across national boundaries. Careful navigation of the patchwork regulatory landscape of the European Union allows for the development of competitive advantages through consolidation of the fertility treatment market.

The rise of IVF market consolidation

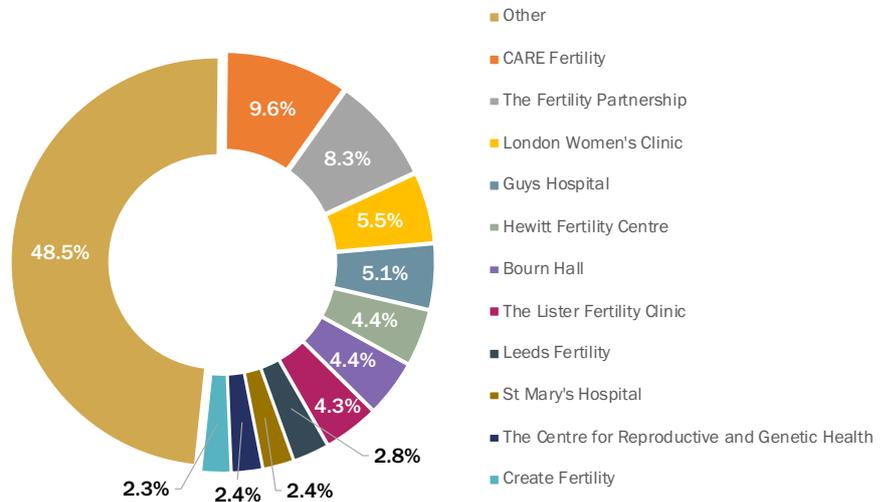
A global trend of increasing infertility rates has been observed over the past 60 years. Within the UK, as many as one in seven couples have difficulty conceiving. Despite this, there have been increasing incidence of patient rejection and NHS IVF cutbacks^{1,2}. It is no surprise then that many patients have turned to the private sector to meet

FIGURE ONE
THE SURGE IN DEMAND FOR IVF HAS BEEN TACKLED BY PRIVATE PRACTICES, WITH THE DEVELOPMENT OF REGIONAL AND NATIONAL FERTILITY CHAINS IN THE UK

TYPES OF FERTILITY CLINICS, NUMBER



IVF + DI TREATMENTS BY FERTILITY CLINIC OPERATOR, %



SOURCE HFEA (2018 DATA); CANDESIC RESEARCH AND ANALYSIS

their treatment needs.

Figure One highlights the distribution of fertility practices between the NHS, research, and private sectors in the UK, illustrating the surge in demand that is being tackled by private practices, with the development of regional and national fertility chains.

The global IVF market was valued at \$18.3bn in 2019 with an estimated CAGR of 9.5% until 2027³. Market growth coupled with the spread and distribution of individual private practices at a national level makes a tempting opportunity for consolidation.

Companies such as Care Fertility in the UK have attempted to capitalise on this growing market through the development and acquisition of 21 clinics around the UK. On a larger scale, the merger of The Valencian Infertility Institute (IVI) and Reproductive Medicine Associates of New Jersey (RMANJ) in 2017 saw the rise of IVI-RMA Global, now one of the biggest providers of infertility treatments globally.

Though the majority of its clinics are located in Spain, IVI-RMA Global has expanded to clinics in the UK, Italy and Portugal among others.

The lack of companies operating beyond national scale is likely due to the inconsistency in IVF regulation across the EU.

However, the few companies like Viva- neo and Eugin beginning to consolidate

across borders suggests there are as of yet untouched competitive advantages

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to operating in multiple locations and not just on a national level.

Navigating the EU regulatory landscape

Astute players will no doubt be aware of the lack of overarching regulation regarding IVF treatments across the EU. Countries within the EU are largely free to enact national legislation that regulates IVF treatment within their borders. A resulting consequence of this lack of overarching legislation is a patchwork in IVF laws leading to key legal differences that shape the landscape of IVF treatment in Europe.

The difference in regulation across borders has far reaching impacts on IVF practices, patients, and consolidators, particularly those attempting to operate outside of a national scale.

Such regulatory variation impacts multiple levels of the industry such as: i) patient eligibility due to age and health, ii) constraints on cell donations, use and banking, iii) procedure and donation reimbursement and iv) limits to pre-implantation genetic testing (PGT). It can be argued that the location of treatment allows patients to select the most convenient jurisdiction depending on their circumstances.

As an example, patient eligibility is one of the key variations across the EU. Age restriction and marital status/orientation are typically the two largest criteria in determining a patient's legal eligibility. Countries such as the UK, Sweden and

FIGURE TWO
VARIATION IN CRITERIA MAKES IT DIFFICULT FOR THOSE SUFFERING FROM INFERTILITY ISSUES TO IDENTIFY AND ACCESS TREATMENTS THAT ARE AVAILABLE TO THEM

TYPES OF RESTRICTIONS FOR NON-PARTNER EGG DONATIONS IN THE EU

	AT	BG	DE	EE	ES	FR	HR	HU	IT	LT	LU	LV	MT	NL	NO	PT	SE	SI	SK
Minimum and maximum age for donation		<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>				<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Non-partner donation is not allowed	<input type="checkbox"/>		<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>				
Number of donations in lifetime		<input type="checkbox"/>													<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Number of children born before the first donation		<input type="checkbox"/>				<input type="checkbox"/>									<input type="checkbox"/>			<input type="checkbox"/>	
Number of inseminations				<input type="checkbox"/>		<input type="checkbox"/>									<input type="checkbox"/>				
Donor residence ¹		<input type="checkbox"/>													<input type="checkbox"/>				
Other restrictions			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				<input type="checkbox"/>		<input type="checkbox"/>			<input type="checkbox"/>		

NOTE 1 E.G. DONORS WITH RESIDENCE IN ANOTHER MEMBER STATE OR THIRD COUNTRY ARE EXCLUDED
SOURCES EUROPEAN COMMISSION REPORT (2016) ON THE IMPLEMENTATION OF THE PRINCIPLE VOLUNTARY AND UNPAID DONATION FOR HUMAN TISSUES AND CELLS

Germany have no upper age restriction on IVF treatments while stricter countries such as Portugal and Greece have an upper limit of 50 years⁴.

Rarely, ‘normal reproductive age’ is used as a guideline wherein the staff on site determine the patient’s eligibility. Coupled with age criteria are restrictions on marital status and orientation. Legal restrictions are placed on the availability of IVF to single women and same sex couples in 32 countries which further restrict the accessibility of IVF.

Such restrictions have led to a surge of fertility tourism due to either lack of options or legal rejection of treatment.

Concomitant to patient eligibility are procurement and utilisation restrictions on cell sources. Sperm and egg donations are permitted in 41 and 38 EU countries respectively, while simultaneous egg and sperm or embryo donations are slightly more restrictive⁴.

Age restriction, number of donations, recipients per donation and number of children also vary on a country by country basis.

Figure Two highlights the variation in laws regarding the types of restriction on non-partner egg donations across

the EU. Naturally, such variation in criteria can make it difficult for those

THE LACK OF COMPANIES OPERATING BEYOND NATIONAL SCALE IS LIKELY DUE TO THE INCONSISTENCY IN IVF REGULATION ACROSS THE EU

suffering from infertility issues to not only identify, but access treatments that are available to them.

Perhaps surprisingly, a significant number of countries across the EU have opted to provide compensation for egg donation. However, a breakdown of the compensations provided reveals an interesting divide.

The majority of compensations are reimbursement costs linked to travel and loss of earnings. A handful of countries such as Spain provide lump sum donor compensation of ~€950. These compensations likely play a large role in the historical differences in egg donor availability compared to countries, such as France, where compensation is forbidden.

While many of these restrictions are prohibitive, savvy navigation of regulatory regions and data analysis will reveal the impetus behind the expansion of companies such as Eugin and IVI-RMA Global.

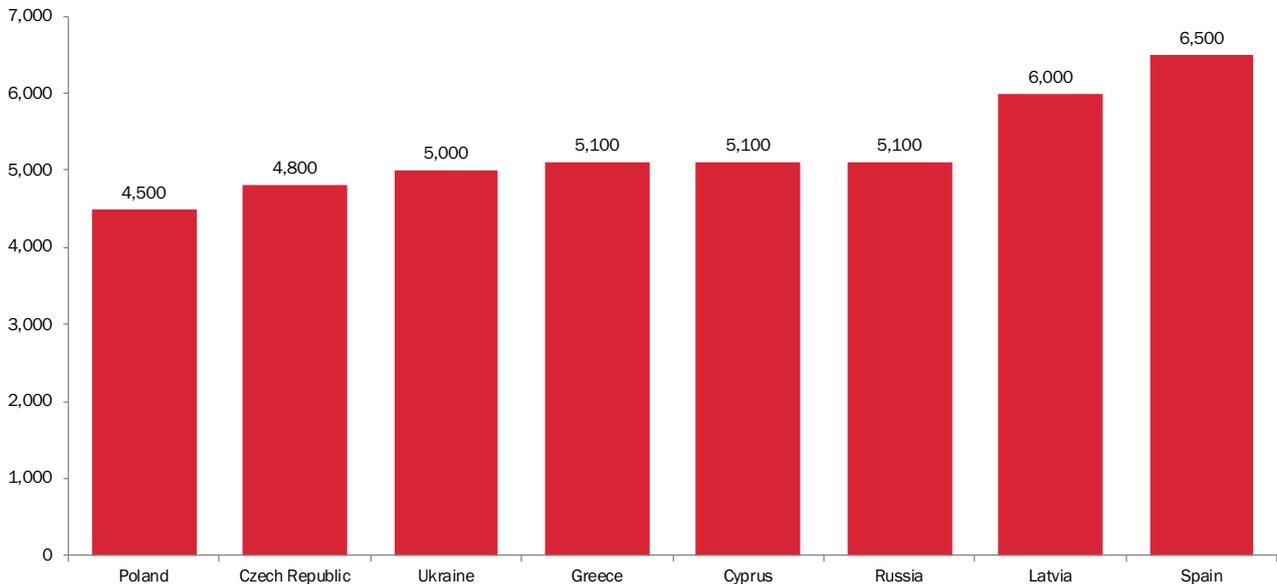
Building a competitive advantage across the EU

Consolidation of individual practices allows for leveraging cost synergies such as sharing of technology, equipment,

FIGURE THREE

THE AVERAGE COST OF EGG DONATION TREATMENT CAN VARY BY 50% IN THE CHEAPER COUNTRIES OF EASTERN AND SOUTHERN EUROPE

AVERAGE IVF EGG DONATION TREATMENT COST, €



SOURCE EGGDONATIONFRIENDS.COM (2018 DATA)

best practices, and unifying methodology to further increase success rates of IVF across all owned practices. Re-branding and acquisition under a single umbrella increases brand impact and trust with consumers while reducing the requirement of multiple independent departments of HR and marketing.

As noted, the EU regulatory patchwork generates swells and dearth of availability and eligibility of donors and patients in respective EU countries. Naturally, these patients seek out private companies abroad that may meet their needs. Companies seeking to consolidate practices must be aware of methods by which they might leverage the observed disconnects between various EU regulation.

Due to the compensation scheme provided to egg donors in Spain, a surplus of donors is available nationally. Donated eggs are associated with increased treatment flexibility and greater IVF success rates. This is largely due to the separation of donor and recipient, allowing for cell storage, increasing availability, flexibility, and commercial applications as a result of the indefinite nature of cell banking. Branching out to countries with more open egg donation and banking laws allows for leveraging the disparity in cell availability to provide customers with the treatments

they seek. Utilisation of this disparity to promote increases in safety are also a possibility. Countries with strict donor policies and flexible cell banking options typically generate higher quality donor eggs, resulting in increased success rates for patients during treatment cycles that may be limited by national law.

Interestingly, despite the surplus of cell donations in Spain, treatment costs are not the lowest in Europe.

Figure Three shows the average cost of IVF treatments in the cheaper Eastern and Southern European countries using donated eggs, taking advantage of a combination of friendlier regulatory environment and lower costs. Making use of not only regulatory differences but cell surpluses and treatment costs between countries in a consolidated enterprise may allow for the distribution of safer, more effective, accessible, and cheaper infertility treatments.

Operators and patients benefit

The EU regulatory landscape is a patchwork of varying laws and restrictions that influence costs, eligibility, and cell availability. Navigating this landscape can be challenging, but savvy

consolidators may develop competitive advantages through regulatory diversification, cost optimisation and unifying methodology. Large scale consolidation efforts can result in cost savings, safer and more available therapies, and greater control of a growing market.

NOTES

- 1 Mackenzie, J. *Women over 34 refused IVF treatment*. BBC News 2018.
- 2 Private IVF Funding: *How to Pay for Private Fertility Treatment* Available online: <https://www.manchesterfertility.com/blog/private-ivf-funding-how-to-pay-for-private-fertility-treatment/> (accessed on Oct 3, 2020).
- 3 In-Vitro Fertilization Market Size | *IVF Industry Growth Report 2027* Available online: <https://www.grandviewresearch.com/industry-analysis/in-vitro-fertilization-market> (accessed on Oct 3, 2020).
- 4 Calhaz-Jorge, C.; De Geyter, C. h; Kupka, M.S.; Wyncs, C.; Mocanu, E.; Motrenko, T.; Scaravelli, G.; Smeenk, J.; Vidakovic, S.; Goossens, V. *Survey on ART and IUI: legislation, regulation, funding and registries in European countries* The European IVF-monitoring Consortium (EIM) for the European Society of Human Reproduction and Embryology (ESHRE). Hum. Reprod. Open 2020, 2020, doi:10.1093/hropen/hoz044