Filippo Maria Ubaldi, Director of the Scientific Executive Committee – GeneraLife

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GeneraLife, an in vitro fertilisation (IVF) clinic group with 14 clinics in Italy as well as in a number of other countries. The group's Director of the Scientific Executive Committee, Dr Filippo Maria Ubaldi, spoke to us about the evolution of reproductive health, Italy's alarmingly low birth rate and the role assisted reproductive techniques can play.

How did you get into the fertility field? Was it your lifelong vocation or did your career path take you in that direction unexpectedly?

Interestingly, I got into this field almost by chance. In those days it was very rare for medical schools in Italy to offer a reproductive medicine specialisation. Yet, as I embarked in my journey as a med student, a young professor of reproductive technology crossed my path proposing me to work alongside him: very naively I accepted without really grasping what it entailed.

Could you give us an introduction to GeneraLife, its mission and vision, and what you do within the company?

GeneraLife is a leading group of in vitro fertilisation (IVF) clinics which focuses on innovation and scientific research in the field of reproductive medicine. The group is rather big: almost 40 clinics in

countries like Italy, Spain, Sweden, the Czech Republic and Portugal. In Italy, we are the largest network of reproductive medicine to date with around 14 clinics all over the country. The group was born in 2020 from the affiliation of several clinics in different countries, guided by the knowledge and experience of the Genera clinics founded back in 2008 by Dr. Laura Rienzi – an internationally acclaimed embryologist – and me. This makes GeneraLife relatively new and with great momentum for growth.

As the director of the scientific executive committee of GeneraLife, my role is to establish and monitor scientific guidelines followed by the individual clinics, as well as guiding the group to new scientific frontiers by staying at the forefront of innovation in the field. As such, our scientific headquarters (HQ) and the scientific direction of GeneraLife is based in Rome.

I value immensely scientific research in this field and it is a founding pillar of the group and, I dare to say, our success. In fact, I try to apply this daily to my work, which has brought me to be a speaker in more than 300 national and international congresses. Moreover, I am currently the chairman of the Italian Society for Reproductive Medicine (SIFES) and I am part of the Technical Committee for the Ministry of Health for Reproductive Medicine.

Are IVF ratios improving with science and medicine?

Since the inception of IVF with the birth of Louise Joy Brown in 1978, more than 8 million babies have been born from this technique and science, medicine and technology have played pivotal role. The milestones have been many from cryopreservation of embryos in 1984, to the introduction of ICSI of 1992 – and I was lucky enough to be working in AZ VUB in Brussels, where this was fine tuned – to uterus transplantation (2015). Additionally, gametes donation has been a gamechanger in the field. Italy has been rather slow compared to other European countries like Spain to assimilate this technique and integrate it in its ordinary practices. Nonetheless, this issue is being pushed forward by experts and hopefully we will be seeing significant progress in the years to come. In fact, as a member of the Technical Committee for the Ministry of Health for Reproductive Medicine, last 29th of June a discussion on the social and medical role of heterologous fertilization in Chamber of Deputies. However, I think it is very important to highlight that nature – or the biological clock of the women – plays a leading role for the success of a live birth. Science and technology have not yet altered how our reproductive system function in this regard: we still must focus on those so-called prime fertility years, when a women is 20-30 years of age, to retrieve eggs of optimal quality**.** Again, technology has aided even in this aspect as today “social freezing” – cryopreservation of healthy eggs – within young women is picking up. Yet, awareness still remains key and we have still have a long way to go before this topic is grasped, and technology fully exploited, by the public.

It seems that fertility became a more talked about topic in the 21st century and therefore innovations in the field appear to be very recent. What scientific discoveries were so revolutionary that changed the field of reproductive medicine forever?

Vitrification and warming procedures for sure, that allow to achieve effective and consistent clinical outcomes and overcome the moral and legal limitation associated with embryo cryopreservation. Then, specific ovarian stimulation protocols that avoid the onset of the ovarian hyperstimulation syndrome, one of the most important complication of the Assisted Reproductive Technique. Or protocols like DuoStim, the ‘double stimulation’ for women with a poor prognosis of response in IVF treatments. And now, Artificial intelligence (AI) could be integrated into assisted reproduction in the near future, ensuring better information about embryo development.

AI is the future of the field. Would you say this path is conducive to the digitalisation of the clinics and pushes for the homogenisation of electronic medical records, telecommunication and other forms of digital advances?

We have seen how this field has been marked by revolutionary discoveries that have helped millions of babies come to life. I am sure that this field still bears new discoveries and progress to be made. As of now, I believe the first game-changer is the networking and homogenisation of protocols, allowing performance to be controlled, which are making IVF clinics operate in a more efficient manner. This will be further improved with the better integration of quality data from clinics that are working in the same manner and following the same protocols, with the help of digitalization.

Moreover, AI will surely enhance other aspects of the field. Personally, I see AI mainly to aid the development of patient-specific treatments and improving gamete and embryo study: the more we understand how embryos behave in vitro, the better we will get at predicting the ones with a reduced chance to become a live birth.

What is the fertility panorama like in Italy?

Today, the fertility panorama in Italy is not shining so brightly: like most industrialised countries, the country is facing a steep, and preoccupying, decrease in the number of newborns. Data from March 2022 illustrates that births have hit an all-time low: in 2021, 385.000 newborns were delivered, comparing this to 1965’s 1.1million newborns, highlights the extent of this crisis. The tycoon Elon Musk recently claimed, Italians could disappear very soon. Although this is slightly too alarming and sensational for the time being**,** the country really needs a wide range of aids for first-time parents and families from an economic, healthcare and occupational point of view. It is also important to expand access to public reproductive medicine services. Medically assisted reproduction scientists have very high standards, but the problem is that not all people can access treatment. The Italian government knows that it is mandatory to implement initiatives that facilitate this access.

Would you say the COVID-19 pandemic has exacerbated the low natality rate in Italy?

I think it is more complicated than reducing it to that. There are social, historical and personal problems that have built up over the decades and led to this situation. In a paper published a few years ago, 5 percent of women were shown to delay pregnancy due to the fact that they had not found the right partner; to that, we should add social and financial uncertainty that in the recent times have been ever so present.

With COVID, the Italian government created “Plan Famiglia” which will include child benefits and investment in daycare and school. Is this enough to impact fertility tendencies in Italy?

This initiative will help, but we need even stronger ones**.** We have examples from other countries like Netherlands or Belgium which have important reimbursements plans for families and we have seen how this has been successful. In Italy, something we have that is exceptional in the European context, is the reimbursement of IVF treatments, assisted reproductive techniques and medications. In Italy, GeneraLife has 2 private centres that are reimbursed and endorsed by their Regions, one in Tuscany and the other in Lombardy. Sadly, the problem remains accessibility: there are long and exacerbating waiting lists, and for families looking to have children, time is a pressing matter. The government is aware of this problem and wants to make it accessible to everybody, but there is still a lot to be done.

Finally, is there anything else you would like to share with PharmaBoardoom’s audience?

I would like to stress that we are in a situation of serious demographic decline, not only in Italy, but in other parts of the world like Japan or Spain. This makes assisted reproductive techniques central in stopping or even reversing this situation. Unfortunately, reports show that in activities in this area have declined during COVID-19 and the decline in newborns continues. We should have, as an advanced western country, a comprehensive plan to use these techniques and sensitise young people on the importance of preserving fertility rates up. As a scientific-focused group of IVF clinics, GeneraLife, for example, focus on information through campaigns that highlight such topics. We offer free consultations during open days, targeting younger women and couples having problems conceiving. We are doing our part and would be eager to collaborate with other like-minded groups.

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