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Press release

The encouraging emerging options in infertility treatments

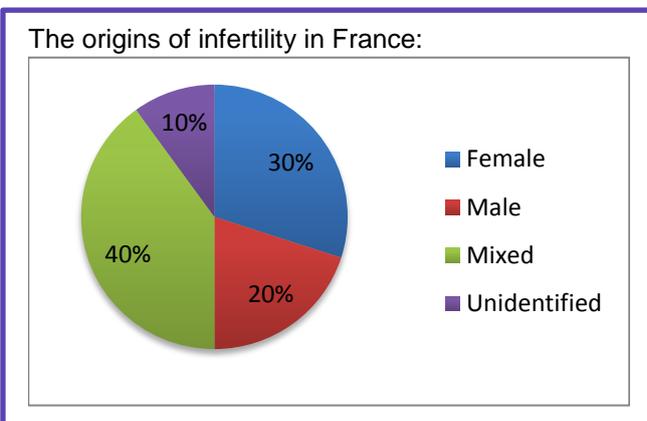
Alcimed, a consulting company specializing in innovation and the development of new markets, takes a look at issues related to infertility and explores the current and future approaches that can provide better support for infertile couples.

Lyon, 1 June 2017 – Infertility is a global health problem that has seen a sharp increase in prevalence over the past 20 years. Today an estimated 80 million couples around the world are affected by infertility problems. In France, the issue concerns one in seven couples, while in the United States one in six couples have difficulties in conceiving.

The progression of infertility is linked to societal change. Environmental factors, such as pollution and endocrine disruptors affect the health of both women and men and may lead to hormonal imbalances or genital pathologies. Then there is also the delay of parenthood for the Y Generation (early 1980 to mid-1990s) putting their careers first, pushing back the desire to have a child into their thirties. Finally, obesity; numerous studies conducted in the United States report a direct link between obesity, hormonal deregulation and infertility.

According to the WHO, **infertility** may be defined as the incapacity to conceive a child after one year of unprotected sexual intercourse. In practice, that period is reduced to six months for women over the age of 35. **Sterility** is a state of infertility that is stable over time, i.e. the couple cannot have children even in the long term.

The path to parenthood



Every case of infertility is different depending on the couple or person and thus each patient pathway needs to be personalized according to the couple's profile. It is with this in mind that MAP¹ centers in France and abroad provide medical assistance to couples in need. In these centers, doctors and biologists specialized in reproductive biology work to identify and assess the origin of infertility. Once they determine whether the origin lies on the male or female side, they will provide the appropriate solution for the couple in question. While for some couples, simple psychological or nutritional assistance may be sufficient, others may

require more complex medical treatments, such as intrauterine insemination (IUI) or in-vitro fertilization (IVF). Depending on the origin of the infertility and the age of the couple, these treatments may require surgery and/or hormone therapy. While in France, social security covers all medical costs for the first six attempts of IUI and the first four attempts of IVF, in the United States and China, medically assisted procreation services are not covered by any public health systems. Thus, the financial aspect of such treatments may constitute a first barrier to parenthood for couples around the world.

The limited success rate of MAP protocols

The second barrier is the low effectiveness of current methods. It is reflected in the coverage of several IVF or IUI attempts in France or by risk-sharing programs called "3 attempts failed = 100%

¹ MAP : Medically Assisted Procreation

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refund² in the USA. After all, MAP is not yet an exact science. In France, the average success rate is 20%³ for IVF and 10.6% for IUI after a first attempt. These rates may vary depending on many factors such as the age of the couple, the origin of the problem, or the MAP center performing the procedure. According to healthcare professionals, this variability between centers but also between couples is a reflection of the limitations of current MAP methods. Two couples with similar profiles will not respond in the same way to the same procedure. Why is that? Has the best embryo been transferred? Was the timing right? Was the patient ready? Can we know in advance if it will succeed? These are all questions that fertility specialists are currently trying to answer. There are still some grey areas in the understanding of some IVF or IUI failures and heterogeneity between individuals in terms of hormonal regulation or genetics as they are all obstacles to understanding fertility problems.

Innovations in the MAP field

Nevertheless, today, numerous avenues are being explored to improve practices in IVF laboratories, to predict the success rate of a procedure and to provide more support for the couples throughout the treatments. As an example, the Montpellier MAP center is developing a 3D embryo modeling tool in order to obtain extensive information on the proper development of an embryo before it is transferred to

Time-Lapse or real-time imaging is a technology that uses a microscope to visualize minute by minute the development of an embryo in the laboratory.

a woman. This technology would make it possible to measure the "health" status of the embryo and to evaluate the potential success of the pregnancy. The choice of the right embryo for transfer is nowadays an important step for biologists. The industrialists in the sector are well aware of this fact thus many visualization and selection tools, such as time lapse microscopes, are emerging. In the same context of assessing the quality of the embryo before its transfer, genetic tests have been developed, particularly in Spain and the USA. The principle is to know if the embryo used for IVF does not have any genetic abnormalities such as a trisomy or a predisposition for a genetic disease. Other genetic tests, such as the ERA⁴ test, can assess the endometrium's receptivity to receiving an embryo, and help doctors choose the time of transfer to significantly increase the chances of pregnancy. Preliminary results show that the pregnancy rate increases by 40% with the use of this type of test. Recently, new technologies have made it possible to launch a smartphone application based fertility test for men. Developed by an American team, this technology allows men to know their fertility level with 98% reliability. This innovation opens the door to new low-cost self-diagnostic tests since the test only requires the use of equipment costing less than \$5⁵.

Due to the limitations of current procedures, many improvements are currently being developed or validated. Nevertheless, the harmonization of MAP protocols at a global level is not yet a reality. National legislation on access to MAP and the use of genetic tests on embryos present real barriers to parenthood for some couples or single individuals. As a result, today, MAP is one of the main reasons for medical tourism not only in Europe but also in the United States and China.

ABOUT ALCIMED- www.alcimed.com

Founded in 1993, ALCIMED is an innovation and new business consulting firm specialized in life sciences (healthcare, biotech, agri-food), chemicals, energy as well as in aeronautics, space, defense and public policy. Today ALCIMED works with major industrial groups, ETIs and SMEs, investment funds and institutional players. ALCIMED relies on a team of 180 highly-skilled individuals to help its clients in the exploration and development of their uncharted territories: New Technologies, Market Innovation, High-Growth Geographies, and Strategic Foresight. ALCIMED is headquartered in Paris and has offices in Lyon and Toulouse in France, as well as in Germany, Belgium, Switzerland, the United-States and Singapore.

Alcimed is a member of CroissancePlus and the ACI (Association des Conseils en Innovation).

² Financial support program providing complete reimbursement to couples, who have not had a child after three IVF cycles

³ Source: Biomedicine Agency report

⁴ ERA : Endometrial Receptivity Analysis

⁵ <http://stm.sciencemag.org/content/9/382/eaai7863>

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