

The FIGO Fertility Tool Box™

http://www.figo.org/news/resources/FIGO_Fertility_Tool_Box

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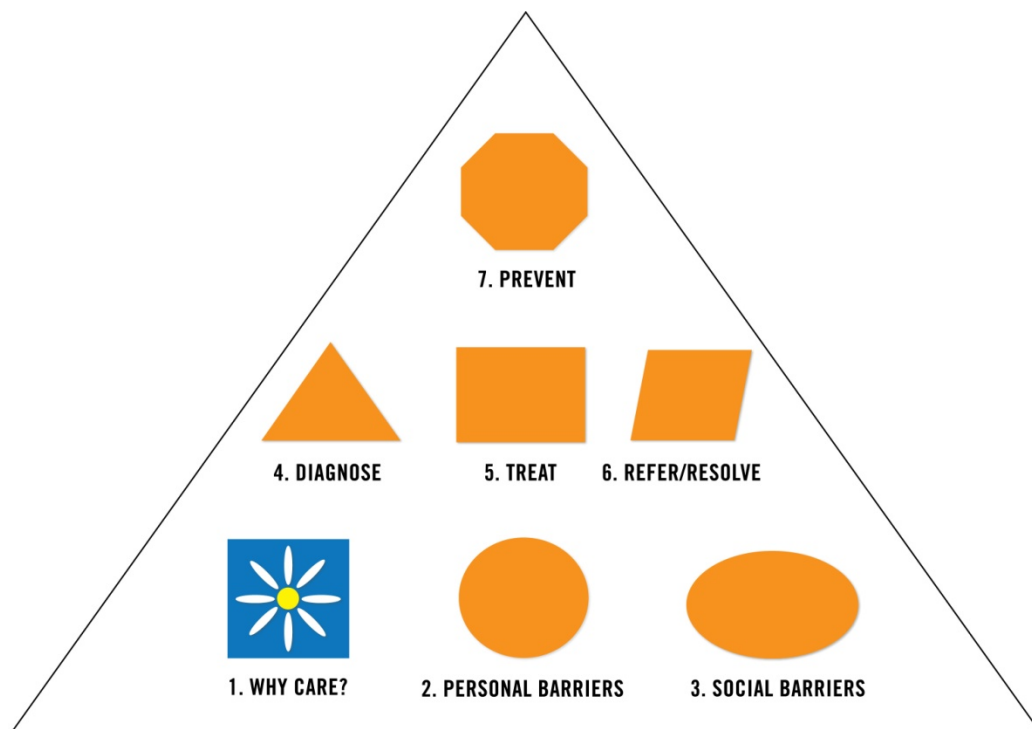
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A Quick Guide to The FIGO Fertility Tool Box™

Who should use it? Anybody who wants to help infertile people! It was designed in the first instance for health care workers, but others who want to make a difference in the lives of infertile people may also find it useful. The Tool Box is available in hard copy but also an electronic version for computers and cell phones.

What's in the Tool Box? Seven Tools to help you tackle the disease/disability of infertility. Each Tool provides information on how to manage a particular aspect of infertility: Tool 1: The FIGO Fertility Daisy – why we should care about infertility; Tool 2: Overcome Personal Barriers; Tool 3: Overcome Societal Barriers; Tool 4: Diagnose infertility; Tool 5: Treat infertility; Tool 6: Refer/Resolve infertility; Tool 7: Prevent infertility. Below is The Tools Pyramid which contains these 7 Tools.

The Tools Pyramid™



How do the Tools work? There are 3 levels of Tools.

The Basic Tools™ contain information that is purposely brief and succinct--just a simple statement or brief summary of the Daisy and each of the six Pyramids of Action. The Basic Tools are colored orange.

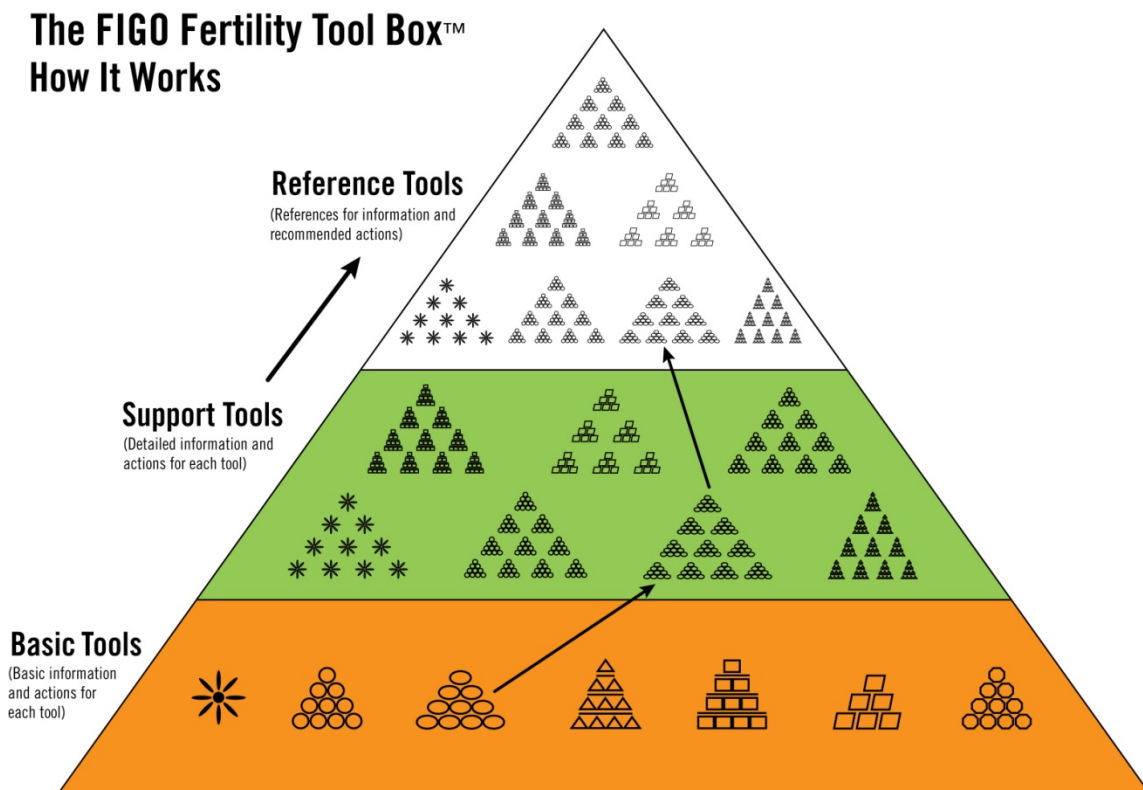
The Support Tools™ provide more information and detail so that you know what to do to take action. Support Tools are colored green.

The Reference Tools™ are lists of references that provide evidence for the information and recommended actions in the Basic and Support Tools. Reference Tools are colored white.

The Glossary provides definitions and explanations of abbreviations and acronyms and is colored white like the References.

By coloring the Levels icons this way, you can always tell whether you are using a Basic Tool, Support Tool or Reference Tool. Below is The Levels Pyramid which shows how the Basic Tools, Support Tools and Reference Tools relate to each other. You can click on the Levels arrow at the top of the page to take you to The Levels Pyramid where you can choose the level you want to work in by clicking that level. You can also choose your level by clicking on The Levels Pyramid icon at the top of each page.

The Levels Pyramid™



How do I know what to do?—The Actions Pyramids: With the exception of the Daisy (Tool 1), all tools have the shape of a pyramid. At the base of each pyramid are Actions that can be taken in low-resource settings, that is, they are often simpler, elementary, involve fewer people and are low-cost interventions or opportunities.

As you move higher up in the pyramid, generally more resources are required to take actions that are usually more complex. You can think of it as a kind of ladder—as you climb higher it usually gets a bit more complex or complicated. Sometimes, however, it might also be easier higher up on the ladder, and the elementary aspects might be those most challenging.

You should do whatever you can do at any level in any of the Tools in The Actions Pyramid. You can click on the Actions arrow at the top of the page to take you to The Actions Pyramid where you can choose the Action you want to work in by clicking the Tool and then the Action in that Tool you wish to do. You can also choose your Action by clicking on The Actions Pyramid icon at the top of each page.

The Actions Pyramids™



7. Prevent



4. Diagnose



5. Treat



6. Refer/Resolve



1. Why Care?



2. Personal Barriers



3. Societal Barriers

Higher-resource and More Difficult Actions at the top of each Tool Pyramid

Lower-resource and Easier Actions at the bottom of each Tool Pyramid

Which Tool should I use? The one you think will work best for you and will give you some results quickly. Doing something is better than doing nothing. There is no right or wrong way to make a start. Then, if you want to do more you can choose other Tools or individual aspects of other Tools to build on what you have already achieved. Or, if you want to be very systematic and are very committed you can start with Tool 1 and work your way through the entire Tool Box.

What if I can't implement some of the recommendations? Then drop it and move onto something that you can do or implement. No single component of the Tool Box is so essential to helping infertile couples that your efforts will fail if you can't apply it. Using even one or two Actions in one or two Tools will empower you to help many infertile individuals.

What if I want to change a Tool? Just do it. The Tool Box is made to be changed so that it can be adapted to work in any type of healthcare setting anywhere in the world. You know what works best in your situation. Just never stop caring and trying to help infertile people.

Does the Tool Box have a compliments and complaints section? Yes, it is called the FIGO Reproductive Medicine Committee. Email us at fertilitytoolbox@figo.org. We would love to hear from you about what you like and what works in the Tool Box works and what doesn't. We hope to constantly improve The FIGO Fertility Tool Box™ to make it a better Tool to help you tackle the disease/disability of infertility.

How To Use

Who should use The FIGO Fertility Tool Box? The FIGO Fertility Tool Box is a “How To” document intended for use by anyone who is involved in or affected by infertility (stakeholders) to provide a comprehensive and integrated set of tools that will increase access to treatment and prevention, and so reduce the global burden of infertility.

It was designed in the first instance for health care workers, but others who want to make a difference in the lives of infertile people may also find it useful. The FIGO Fertility Tool Box is directed towards mid-level primary women's healthcare practitioners who can provide reproductive healthcare services, namely women's health nurses, midwives, and obstetricians/gynecologists. However, the Tool Box can also be used by healthcare personnel without medical training, be they in policy/government/organizational positions or lesser trained women's healthcare providers, including lay providers and support groups. Different Tools are intended for use as appropriate and possible by stakeholders in their unique situations.

The Tool Box is available in hard copy but also an electronic version for computers and cell phones.

Clicking on your computer or cell phone in The FIGO Fertility Tool Box™ The FIGO Fertility Tool Box is available in paper or hard copy as well as a program for your computer, or application (“app”) for your cell phone. In the paper version, the Tool Box has these initial instructions first (Home), followed by more detailed instructions (How To) and then the 7 Tools in order, each one starting with the Basic Tool, then the Support Tool and then the References. After the 7 Tools is a section with all the references that also contains Recommended Reading and a Glossary. At the end is a section on About Us. You can look through the hard copy version just like a book to find whatever Tool, Level and Action you want to do.

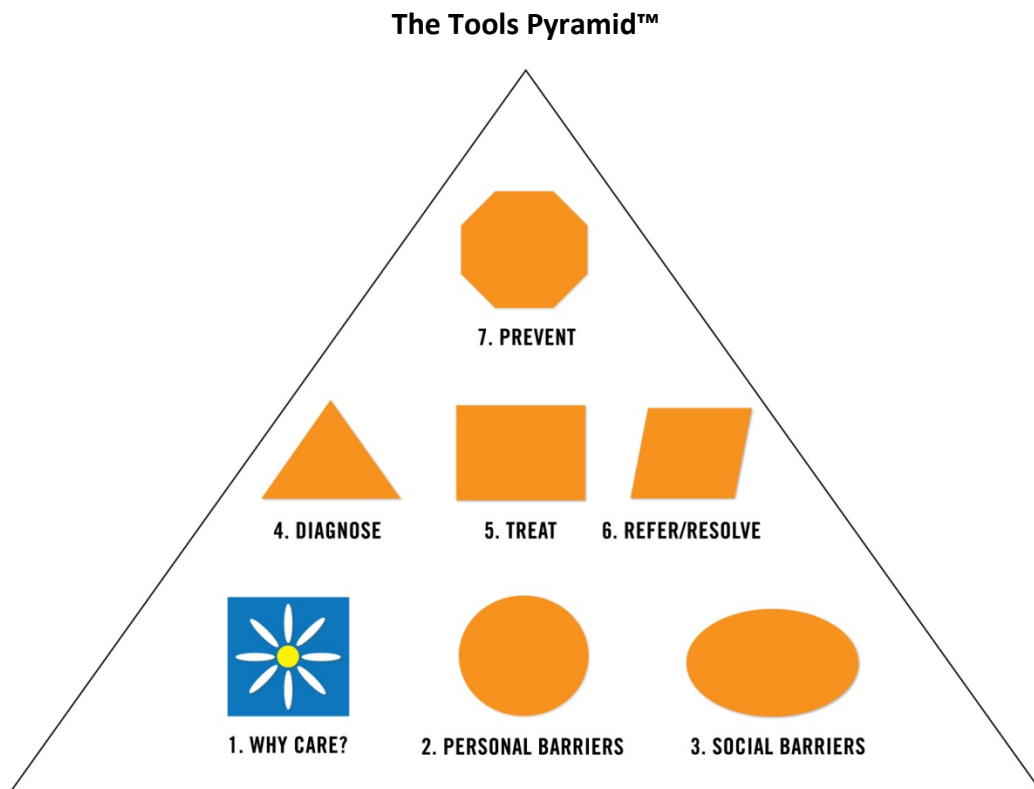
In the electronic and cell phone app version, you can click on the Tools arrow at the top of the page that will take you to The Tools Pyramid where you can choose the Tool you want to use by clicking on that Tool. You can also click on the Levels arrow to go to The Levels Pyramid™ to choose the level you want, or you can click on the Actions arrow to go to The Actions Pyramid™ to choose the Action you want to do. The Tools, Levels and Actions are described in more detail just below.

To make it even easier, you can click on the small pyramid icons at the top of each page to choose your Tool, Level and Action. Or you can also choose from a written list in the left hand column. Use whatever clicking method works best for you. Try it out and you will see how easy it is to find what you want quickly so that you can help infertile people.

What's in the Tool Box? The FIGO Fertility Tool Box contains 7 Tools to help you tackle the disease/disability of infertility. Each Tool provides information on how to manage a particular aspect of infertility: Tool 1: The FIGO Fertility Daisy – why we should care about infertility; Tool 2: Overcome Personal Barriers; Tool 3: Overcome Societal Barriers; Tool 4: Diagnose infertility; Tool 5: Treat infertility; Tool 6: Refer/Resolve infertility; Tool 7: Prevent infertility.

These tools provide a comprehensive approach to infertility as both an individual and a global disease/disability. Each Tool is represented by a pyramid, except for Tool 1, The FIGO Fertility Daisy, which is different and addresses why we should care about infertility. Each pyramid consists of multiple elements all of one shape that is unique for each tool. These elements each reflect one situation/action that is important and can be dealt with using the “Tool” in that element.

Below is The Tools Pyramid™ which contains these 7 Tools.



The FIGO Fertility Tool Box is intended to empower people to take action in their setting. It is based on the best available evidence, comprehensive, integrated and easy to use. It involves teaching, but the primary objective is to empower action, especially through collaboration with other interested people.

The FIGO CRM recognizes and appreciates the vastly different socioeconomic, cultural, religious, healthcare system and other differences among and within the 124 FIGO country members. Therefore, The FIGO Fertility Tool Box focuses on universal principles, recognizing that each country and region will decide how to utilize this resource in a unique way that is most appropriate for them. In other words, it has been designed for maximum flexibility in its application by many different stakeholders, in addition to healthcare providers, in many different global situations.

Importantly, the Tool Box is not intended to address the more sophisticated infertility treatments, despite their importance in managing infertility, but it does include Tool 6. Refer/Resolve with instructions on how and when to refer to these resources.

Therefore, major principles of the Tool Box are: it is focused on low-resource settings; it is flexible so that it is applicable in almost any country of the world; it is aimed primarily at mid-level practitioners such as nurse-practitioners and midwives; it is usable by all types and levels of healthcare professionals, stakeholders, policy-makers and patients; it is easily distributed electronically and with mobile applications; it takes advantage of technology innovations; sufficiently innovative to be interesting.

How do the Tools work? There are 3 levels of Tools for each of the 7 Tools.

Each of the 7 Basic Tools™ contain information that is purposely brief and succinct--just a simple statement or brief summary of the Daisy and each of Actions described in the six Actions Pyramids. These Actions describe the most basic Actions that can be done to increase access to and quality of infertility care. The purpose of The Basic Tool is to ensure that all stakeholders, even those with little education or training, are aware of all aspects/elements of issues that must be addressed. The Basic Tools icons are colored orange so that you know when you are using a Basic Tool.

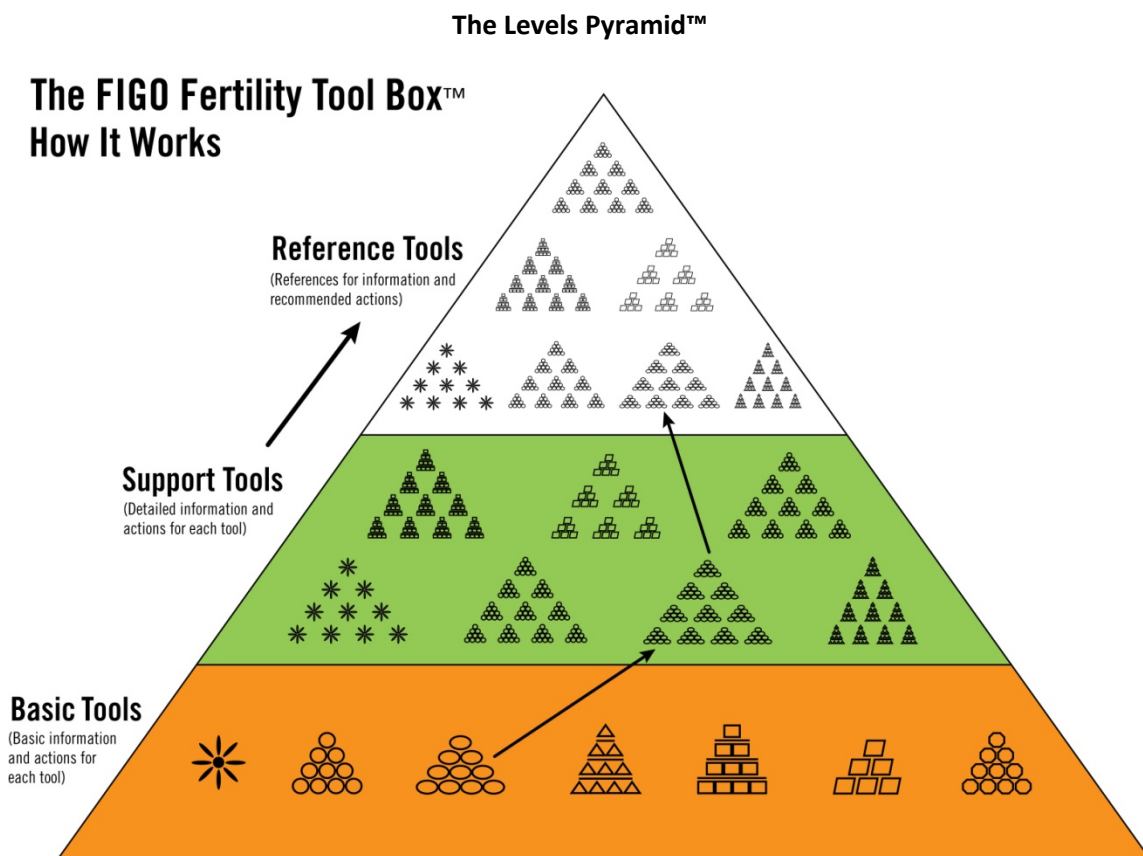
Each of the 7 Support Tools™ provide more information and detail so that you know what to do to take Action. Support Tools are the next highest in the hierarchy/level and consist of text approximately one page in length for each of the aspects/elements identified in the Basic Tool shapes and for which an Action is recommended. The Support Tools are linked directly to their respective Basic Tool shapes in their respective pyramid figures by small icons whose shapes and colors designate the tool in which they belong and their position in the pyramid, reflecting the level of complexity of the activity and resources required to perform it. The Support Tool describes in more detail the aspect of infertility care being addressed, provides references using the best available evidence and describes how to take an Action. For clinical care, details of diagnosis, treatment, referral/resolution and support are described at the level of a mid-level provider such as a nurse practitioner or midwife who is not a physician. However, the Support Tools may be learned by interested individuals and/or used for teaching and can also be a useful guide for well-educated healthcare providers not familiar with infertility. Support Tools are colored green so that you know when you are using a Support Tool.

The Reference Tools™ are lists of references that provide evidence for the information and recommended Actions in the Basic and Support Tools. Reference Tools are colored white. Reference Tools reflect the top level of the hierarchy of Tools. References are used to justify the statements and recommendations in the Support Tools. Only the best available evidence from important references from meta-analyses, highly regarded journals, professional organizations and/or significant national or international organizations are used. The FIGO CRM has utilized and referenced the expert work of

other organizations, including the WHO, ASRM, ESHRE, IFFS and others. In several instances evidence was surprisingly scarce; in those situations individual papers were sometimes used because they had a pertinent message relevant for our tool box. The Reference Tools include citations of all the references used in the Support Tool. It also includes links to full-text manuscripts/articles of all the references when possible. Reference Tools also include a section titled Recommended Reading that includes additional sources of information that might be useful for anyone wishing to learn more about the statements and information in the Support Tool and/or want to learn more about infertility.

A Glossary is found after The Reference Tool. The Glossary provides definitions and explanations of abbreviations and acronyms and is colored white like the References.

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How do I know what to do?—The Actions Pyramids: With the exception of the Daisy (Tool 1), all tools have the shape of a pyramid. At the base of each pyramid are Actions that can be taken in low-resource settings, that is, they are often simpler, elementary, involve fewer people and/or are low-cost interventions or opportunities.

The Actions at the base of the pyramid reflect initial situations/actions that require very few resources, often just an interested person even without financial resources who is functioning at the lowest healthcare level or even outside the healthcare system. It tells them “What to do” even in the lowest resource settings. The intermediate level of situations/actions are higher in the pyramid and reflect a greater need for some type of resource, be it institutional, personnel and/or financial in order to take

action. The top of the pyramid Actions reflect activities/actions that need highly trained/specialized personnel, institutions, healthcare or societal systems or financial resources. This structure of a hierarchy or levels represents a continuum of care, not a categorical one, so as to take into account the wide variety of situations among and within different countries.

As you move higher up in the pyramid, generally more resources are required to take Actions that are usually more complex. You can think of it as a kind of ladder—as you climb higher it usually gets a bit more complex or complicated. Sometimes, however, it might also be easier higher up on the ladder, and the elementary aspects might be those most challenging. Your goal is to do whatever you can do at any level in any of the 7 Tools in The Actions Pyramid.

The Actions Pyramids™



7. Prevent



4. Diagnose



5. Treat



6. Refer/Resolve



1. Why Care?



2. Personal Barriers



3. Societal Barriers

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The Tool Box is intended for use by all stakeholders in different professions (e.g. clinical, policy makers, patients, others) at all different levels of education and training in all types of low to high resource settings. Different parts of the Tool Box can be used by different individuals attempting to provide access to quality fertility care.

All stakeholders can quickly get a comprehensive overview of all aspects of fertility by reading each Basic Tool section of the 7 tools. This will give an initial overview of all aspects of fertility. Stakeholders who want to take an action can use the appropriate Support Tool that applies to the situation/problem they are addressing. The Support Tool provides all the information necessary to empower an individual to take action and do something. Those who are able to utilize higher resource information can use the Reference Tool to learn and do more.

What if I can't implement some of the recommendations? Then drop it and move onto something that you can do or implement. No single component of the Tool Box is so essential to helping infertile couples that your efforts will fail if you can't apply it. Using even one or two Actions in one or two Tools will empower you to help many infertile individuals.

What if I want to change a Tool? Just do it. The Tool Box is made to be changed so that it can be adapted to work in any type of healthcare setting anywhere in the world. You know what works best in your situation. Just never stop caring and trying to help infertile people.

Future Development of The FIGO Fertility Tool Box™. The FIGO CRM will develop a questionnaire/survey to obtain feedback on use of the Tool Box. Blogs, social media and field testing through FIGO national societies and thought leaders will be pursued. The FIGO CRM will evaluate feedback, modify the Tool Box to keep it standardized but evolving, facilitate discussion and dissemination of ideas to and among stakeholders, and facilitate national/regional modifications to enhance the Tool Box. It is intended that The FIGO Fertility Tool Box™ will be modified based on experience with its use in the many unique conditions that exist globally and evolve over time to become an increasingly useful and dynamic tool that increases access to quality infertility care globally.

Does the Tool Box have a compliments and complaints section? Yes, it is called the FIGO Reproductive Medicine Committee. Email us at fertilitytoolbox@figo.org. We would love to hear from you about what you like and what works in the Tool Box works and what doesn't. Let us know how you are using it and how you are changing it. We hope to constantly improve The FIGO Fertility Tool Box™ to make it a better Tool to help you and all healthcare workers and other stakeholders tackle the disease/disability of infertility.

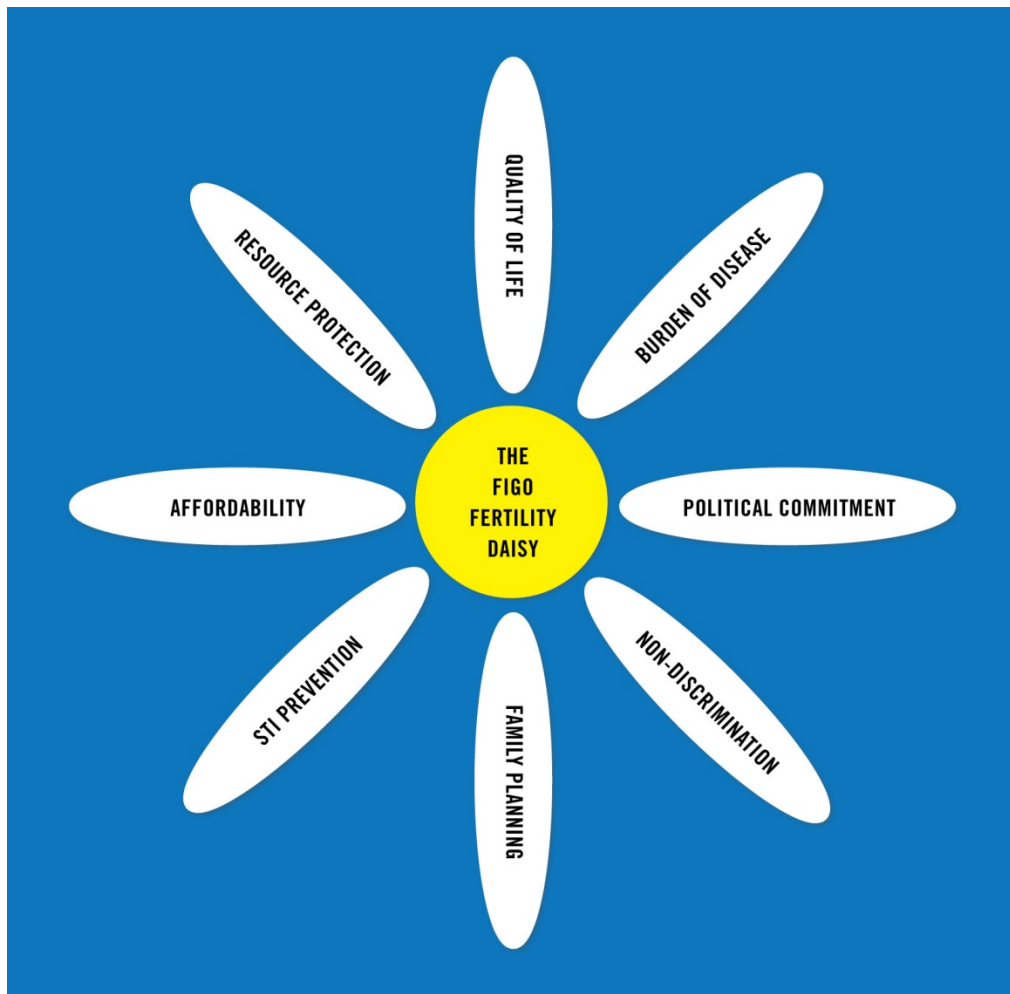
Tools

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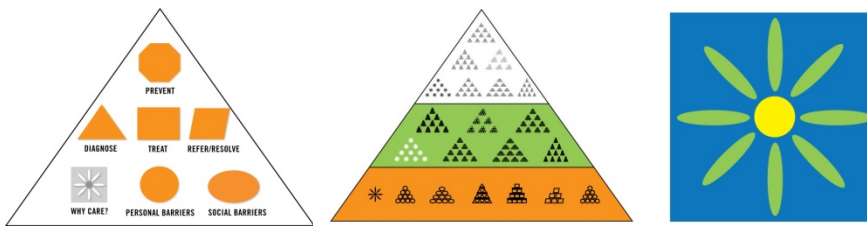
FIGO FERTILITY TOOL 1: WHY YOU SHOULD CARE ABOUT INFERTILITY

BASIC TOOL 1: THE FIGO FERTILITY DAISY—WHY SHOULD I CARE?



1. **Quality of Life:** Infertility reduces quality of life, especially through negative psychosocial consequences. These range from fear and depression to stigmatization and lost dignity in death. In developing countries the negative consequences of childlessness are more frequent and more severe.
2. **Burden of disease:** Globally an estimated 9% of women of reproductive age suffer from infertility. This equals 80 Million women.

3. **Political Commitment:** Nations around the world have committed to the Millennium Development Goals (MDG). Absence of infertility treatment is a relevant barrier to universal access to reproductive health (MDG 5).
4. **Non-discrimination:** Children can thrive or suffer in all social classes. The rich are not more deserving of reproduction than the poor. Infertile people are as deserving of health care as those with other diseases.
5. **Family Planning:** The integration of infertility management into Family Planning/ Reproductive Health/Women’s Health services mutually strengthens these services.
6. **STI/HIV Prevention:** Infertility is a risk factor for STI/HIV acquisition. Infertility management helps to combat the STI/HIV pandemic.
7. **Affordability:** The cost of infertility treatment is a continuum from the cost of fertility advice to the cost of ART. Effective interventions in the lower cost range are affordable in many health settings.
8. **Protection of Resources:** Absence of appropriate infertility management fosters ineffective interventions which squanders precious resources of health systems and households.

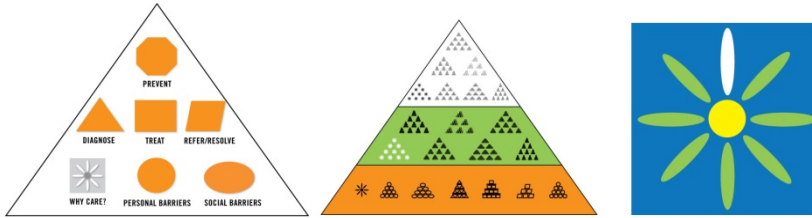


SUPPORT TOOL 1

THE FIGO FERTILITY DAISY—WHY SHOULD I CARE?

Infertility is a disease/disability that is poorly understood or appreciated by most people who have not suffered from it. As a result, there is generally not much emotional or other support for women and men with infertility, and commonly not much empathy. This causes the distress and burden of infertility to be even greater for the infertile and results in them usually having to deal with this crisis in their life emotionally isolated and without familial or societal support. Furthermore, society as a whole generally does not provide financial support for diagnosis and treatment, so that solving the problem is even more unlikely.

However, infertility is a very significant disease/disability that deserves recognition and support from society. Each individual and society should care about infertility and infertile women and men for many reasons which are described in this tool.



1. Quality of Life: Infertility reduces quality of life, especially through negative psychosocial consequences. These range from fear and depression to stigmatisation and lost dignity in death. In developing countries the negative consequences of childlessness are more frequent and more severe.

Infertility is a disease/disability that is both a health problem and a social problem. WHO has defined infertility as a disease, thereby recognizing that infertility seriously affects a person’s health. (ICMART and WHO, 2009) Unfortunately many people and countries continue to think of infertility as a mere personal wish and as such give it little priority in their health systems. (ESHRE Taskforce Ethics & Law, 2009) Infertility has also many negative psychological and social consequences including marital instability, anxiety, depression, social isolation and deprivation, loss of social status, loss of gender identity, ostracism and abuse. Most religions place a high value on children, and infertility may affect a person’s religious or spiritual well-being in life and even after death. (Dyer, 2007; van Balen and Bos, 2009) Social consequences such as marital conflict or deprivation may in turn impact on health (for example through exposure to sexually transmitted disease or poverty-related illness), thus creating a vicious cycle between social and health consequences secondary to infertility.

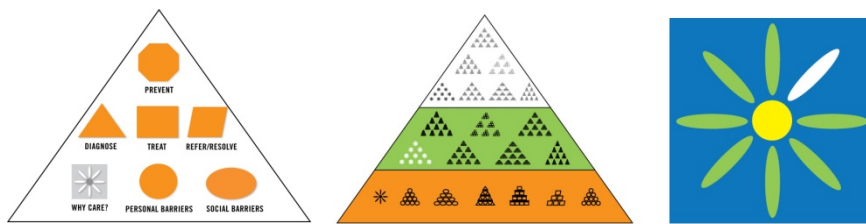
To some extent these consequences are rooted in the fact that especially in developing countries, infertility violates a social norm of having (many) children. The violation of a social norm, even if unintended, results in stigmatisation. Others may think of an infertile person as having less worth as a woman, a man or an adult, and infertile people may think of themselves as being inferior to somebody with children. This can cause loss of self-esteem and self-worth and give rise to ostracism, neglect, deprivation and abuse.

The many negative psychological, social and cultural consequences have been classified into six stages. (Daar and Merali, 2002) These levels reflect both the continuum and the multiplicity of harm inflicted by infertility.

Level 1	Guilt, self-blame, fear
Level 2	Marital stress, economic stress, helplessness, depression
Level 3	Mild marital or social violence and abuse, serious economic hardship social alienation
Level 4	Moderate to severe marital or social violence and abuse, severe economic deprivation, social alienation and abuse culminating in loss of social status

Level 5	Death through violence-induced suicide, starvation, disease
Level 6	Lost dignities in death

Increasingly, health-systems focus on quality of life and well-being, and not only on morbidity and mortality. Several instruments exist which seek to measure quality of life (QoL) and compare QoL between people living with different diseases. At present many of these instruments do not capture the true extent of the experience of infertility. It is important that researchers find a way to appropriately document the QoL of people suffering from infertility and to inform health politicians and planners of the finding. In this way limited resources can be allocated more fairly and equitably.

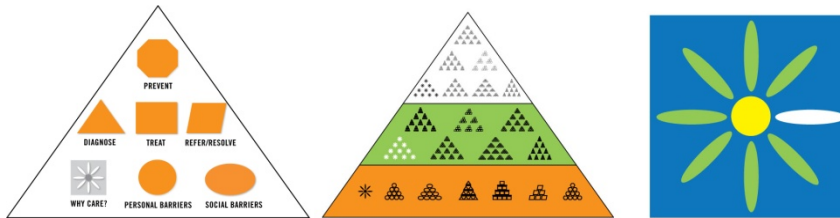


2. Burden of disease: Globally an estimated 9% of women of reproductive age suffer from infertility. This equals 80 Million women.

The prevalence of infertility can only be estimated. Estimates vary considerably depending on the criteria used to define infertility and the population sampled. One review, using data from published population surveys on infertility, reported that globally an estimated 9% of women of reproductive age suffered from infertility, amounting to 72.4 Million women worldwide (Boivin et al, 2007). Experts anticipate that this prevalence will rise further if women increasingly postpone child bearing until later in life. Another report, evaluating data from demographic health surveys, concluded that in developing countries alone more than 186 million ever-married women age 15-49 suffered from primary or secondary infertility (Rutstein and Shah, 2004). While it is desirable to get more precise and consistent estimates in future based on consensus regarding definitions and sampling methods), discrepancies in estimates should not deter from a simple truth, namely that infertility is a common reproductive health disease/disability affecting millions of women and men worldwide (Gurunath et al, 2011).

Paradoxically, high infertility rates are often observed in countries which also have high total fertility rates. This paradox can be explained by sexual behaviour which is orientated towards having (many) children (e.g. early age at marriage, universal marriage, low use of contraception) in settings where there are also many risk factors for infertility (e.g. high prevalence of sexually transmitted diseases, formal and informal polygamy, poor pregnancy care with high rates of pregnancy-related sepsis). Thus many developing countries have a problem of both over-population and infertility. Infertile people living in these countries suffer particularly as they are often ostracised in the family and community, as well as in health systems which do not allocate resources to infertility.

Prevalence is one of two factors determining the burden of disease. The other factor is quality of life. Conditions which have a high prevalence and which impact very negatively on quality of life give rise to a high burden of disease. The burden of disease associated with infertility has not been accurately estimated. But because infertility is a very frequent condition and can seriously impact on people's lives, the disease burden of infertility is likely to be significant.



3. Political Commitment: Nations around the world have committed themselves to the Millennium Development Goals. Absence of infertility treatment is a relevant barrier to universal access to reproductive health (MDG 5).

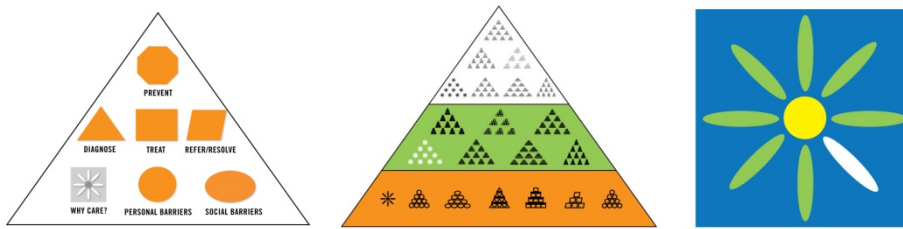
Governments around the world, from both rich and poor countries, have repeatedly committed themselves to provide reproductive health care for their people. At the 1994 International Conference on Population and Development in Cairo, 180 national governments recognised and agreed that reproductive health was a state of complete physical, mental and social well-being and not merely the absence of disease. Governments committed themselves to a programme of action which called for universal access to reproductive health services. Infertility prevention and treatment was explicitly acknowledged as integral components of such services.

In 2001, less than 10 years later, nations made an even bigger commitment to a series of international development goals relating to reduction in poverty, access to primary education, improvements in health as well as environmental sustainability. The goals, which have come to be known as the Millennium Development Goals (MDG), reflect an unprecedented global consensus on priorities for human development (Waage et al, 2012). They also represent a partnership between rich and poor countries to achieve targets by 2015. MDG 5b is the goal to achieve universal access to reproductive health.

National and international task teams are working towards these goals. Rich countries are providing significant development assistance, while recipient countries are responsible for strengthening their health systems and for ensuring that allocated resources truly translate into better health, especially for the poor.

Progress towards the MDGs has been patchy and clearly not all goals will be reached, and not in all regions. The MDGs in general, and MDG5b specifically, are not only a goal to be taken literally, but also as a 'symbol' for a future outcome towards which to strive. The MDGs have therefore been described as a tool, a tool that galvanizes action, generates discussion, attracts and directs attention, and holds leaders accountable (Clemens et al, 2007). The FIGO Fertility tool box is developed with similar objectives in mind.

People wishing to improve access to quality infertility care in their countries have a unique opportunity to do so now, calling on political promises and willingness and using MDG5b both as a goal and tool. The FIGO Fertility Toolbox helps to outline the task at hand.



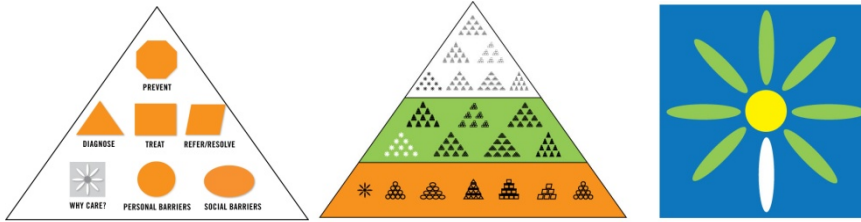
4. Non-discrimination: The rich are not more deserving of reproduction than the poor. Infertile people are as deserving of health care as people with other diseases.

There are wide disparities in the delivery of infertility services between developed and developing countries (Nachtigall, 2006). Poorer countries usually have few or no infertility services. Where services exist, they are often more difficult to access and are of lesser quality when compared to rich countries. In addition, there are often wide disparities between more and less affluent people in the same country regarding the type and quality of infertility care that can be accessed. As a result the majority of the world's poor suffer from infertility without hope for effective treatment, while the more affluent can often access modern interventions either in their own country or through cross-border care. This is a major violation of social justice (Inhorn, 2009).

People, organisations and governments may try to justify this social injustice by stating that in low resource settings infertility services are not important or not needed because of overpopulation and high fertility rates. Such statements discriminate unfairly and unnecessarily against infertile people. Firstly, fertile and infertile people should contribute equally to the reduction of population growth. Secondly there are better ways of reducing high global fertility rates than by denying infertile couples access to treatment (ESHRE Taskforce on Ethics & Law, 2009).

People, organisations and governments may also argue that infertility services are not feasible because other, seemingly more important, health issues such as HIV/AIDS or maternal mortality use up all resources. This approach ignores the suffering associated with infertility. In addition, resources are often directed not only to other health needs but to other governmental projects, and these should also come under scrutiny when discussing limited resources. Governments must, of course, prioritize the allocation of (health) resources, but this should not result in the complete exclusion of one group of patients (ESHRE Taskforce on Ethics & Law, 2008; ESHRE Taskforce on Ethics & Law, 2009). Some form of relatively inexpensive infertility service is feasible in many low resource settings.

Lastly, lack of commitment to infertility care may also reflect the view that poor people do not deserve assistance with reproduction because their offspring have high morbidity or mortality or suffer otherwise from neglect. Truly, assistance with procreation should not be offered if there is a high risk that the future child will die prematurely or be seriously neglected. But extrapolating this argument to all people who live under compromised conditions is discriminatory and therefore unethical.



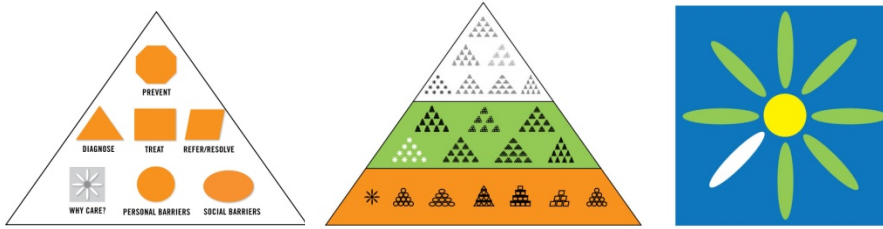
5. Family Planning: The integration of infertility management into Family Planning/ Reproductive Health services mutually strengthens these services.

“Family planning must also mean planning for families” (Mahmoud Fathalla, former president of FIGO).

Contraceptive methods reduce the risk of subsequent infertility by preventing unwanted pregnancies and the ensuing risks associated with unsafe abortion. Additionally, irrespective of their contraceptive efficiency, barrier methods reduce the risk of sexually transmitted diseases and pelvic inflammatory disease which may cause tubal factor and male factor infertility. Therefore universal access to quality contraception services will reduce the prevalence of infertility and thus form part of an infertility prevention strategy.

The fear of infertility is, however, an important barrier to the use of contraception in many developing countries. Studies from sub-Saharan Africa describe that many women and men believe that the use of contraception can cause permanent sterility (Dyer et al, 2002; Koster-Oyekan, 1999; Upton and Dolan, 2011). At the same time existing family planning services usually promote pregnancy prevention but have little to offer those desiring fertility. The fear of contraception-induced infertility combined with the lack of infertility management undermines the use of contraception.

By incorporating the planning for families into existing family planning and reproductive health services, relevant advances in reproductive health can be achieved. Infertility management will include counseling patients that contraception does not cause infertility but rather prevents it, while at the same time offering infertility treatment or referring for such treatment. The same services will continue to promote contraception, sexual health, and planned parenthood. This integrated approach is likely to improve patient satisfaction, contraceptive use and overall reproductive health.



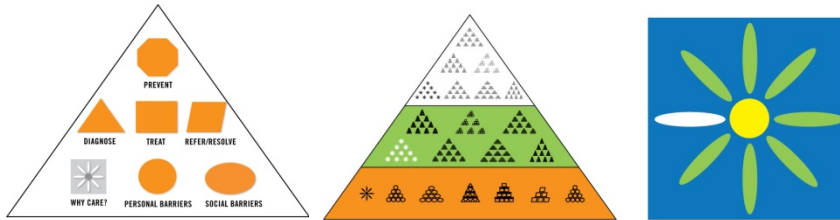
6. STI/HIV Prevention: Infertility is a risk factor for STI and HIV acquisition. Infertility management helps to combat the HIV pandemic.

Sexually transmitted infections including HIV/AIDS are an important cause of infertility and reproductive ill health in developing countries, especially in sub-Saharan Africa which carries a large burden of the global HIV pandemic. HIV infection reduces human fecundity through gonadal dysfunction, tubal infection, pregnancy loss and infant death. STIs/HIV are therefore important risk factors for infertility, and STI/HIV prevention and early treatment of STI can prevent infertility.

At the same time, infertility is a risk factor for STIs and HIV infection. This is because infertility frequently causes marital instability in developing countries. According to evidence women with primary infertility are between 14% and 40% more likely to be divorced or separated than fertile women. Infertility significantly increases the likelihood of men marrying a 2nd woman in societies where polygamy is allowed. Infertility is also associated with extra-marital relationships, the prevalence of which is unknown, and can lead to prostitution when abandoned women are left economically destitute (Inhorn, 2009).

The social consequences of infertility therefore induce behaviour that exposes men and women to STI/HIV, and higher rates of HIV infection among infertile women when compared to pregnant women have been documented.

In view of the high prevalence of infertility and the associated high-risk sexual behaviour, infertility has been considered a driving force of the HIV epidemic in sub-Saharan Africa, with possible similar dynamics in other regions. Therefore infertility management, through a possible stabilising effect on marriage, may help to combat the STI/HIV pandemic.

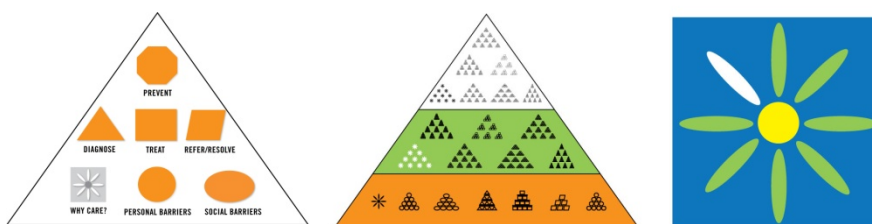


7. Affordability: The cost of infertility treatment is a continuum from the cost of fertility advice to cost of ART. Effective interventions in the lower cost range are affordable in many health settings.

The absence of appropriate infertility care is often rationalised by the high cost of ART. ART may indeed not be affordable for those in low socioeconomic groups in rich and poor countries, but this does not explain or justify why other less costly interventions are not offered to couples who may not require ART in order to conceive. Fertility advice, including advice on healthy life style, costs the time of the health care worker but requires no additional resources. Other interventions such as clomiphene citrate and intra uterine insemination can be offered without major cost and without the need for expensive laboratories and equipment. The relative absence of infertility care in many developing countries is more often due to a lack of political willingness and planning, than due to lack of resources for ART (Inhorn, 2009).

Infertility care without ART cannot help all infertile couples, but evidence-linked, basic and affordable interventions will be of benefit to many. At the same time it signals an important step away from inaction and absence of care.

In better resourced settings ART may become available. The lower the cost the more accessible and affordable ART will be for both patients and health systems. Research needs to focus on safe, low-cost modifications of standard ART. In the meantime practitioners have a recognised duty to their patients and the health care system to offer care at the lowest cost reasonably possible (ESHRE Taskforce on Ethics & Law 2008; ESHRE Taskforce on Ethics & Law, 2009).

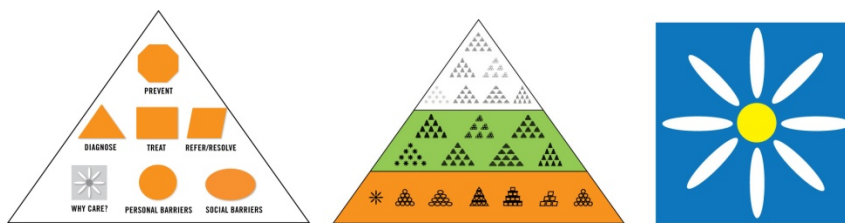


8. Protection of Resources: In the absence of appropriate infertility management, ineffective interventions are tried. This wastes precious resources of health systems and households.

Many infertile couples seek help relentlessly in the hope to conceive. In developing countries infertility is a frequent reason why women access bio-medical as well as traditional health services and keep doing so over time. Infertile women do not simply disappear from the health sector, if appropriate infertility care is not available. Instead, often ineffective and possibly harmful forms of treatment are tried.

There is an overall lack of data on the financial impact of infertility care on households. A few studies describe how infertile women use their meager resources, and at times all their resources, on infertility treatment which may involve ineffective medication or surgical interventions as well as various forms of traditional therapies (Dyer and Patel, 2012). Similarly, the waste of resources in the health sector has not been systematically explored but available evidence suggests that the amount is likely to be relevant and significant. Therefore both the patients and the health sector lose resources which they can ill afford to lose (Dyer and Pennings, 2010).

Moreover, it has been recognised that health systems do not only have the responsibility to provide health services, but also to protect households that are accessing their services from impoverishing out-of-pocket payments which may cause or deepen existing poverty. (Xu et al, 2002; ESHRE Taskforce on Ethics & Law, 2008) In other words health systems should protect the resources of their citizens, especially those who are poor. Health systems in poor countries are at risk of failing twice in their responsibility towards infertile women: (1) by not offering access to quality reproductive health care and (2) by not helping to protect infertile couple's or women's resources from possibly crippling out-of-pocket expenditures.



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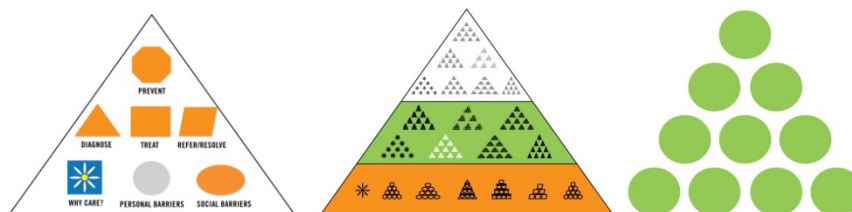
THE FIGO FERTILITY TOOL 2: HOW TO OVERCOME PERSONAL/PATIENT BARRIERS TO FERTILITY CARE



BASIC TOOL 2: HOW TO OVERCOME PERSONAL/PATIENT BARRIERS TO FERTILITY CARE

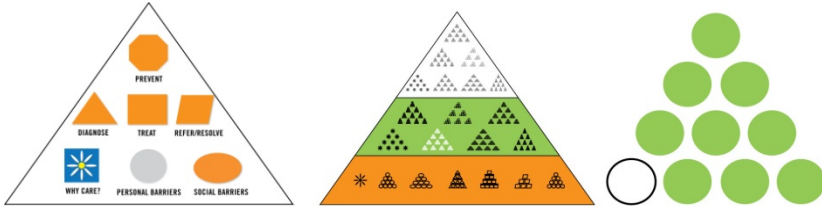
1. Recognize personal and patient barriers to accessing care: Personal cultural, religious and family values that prevent access or limit care need to be recognized and resolved by the untreated infertile, by patients and by care providers.

2. **Detail cost barriers:** The cost of initiating investigations and treatment for infertility is often not covered by available state health services and may require out of pocket payment. This can deter couples from seeking help for infertility.
3. **Address distance barriers:** Geographical factors can influence health seeking behaviour in circumstances where basic infrastructure in terms of roads and transport are suboptimal.
4. **Identify family/community barriers:** Infertility is regarded in many communities as a personal issue and declaration by couples of their infertile status can lead to stigmatisation.
5. **Identify available technology and services:** Although assisted reproduction requires sophisticated technology, basic investigations and treatment for infertility may be available in less resource rich settings.
6. **Identify accessible, affordable treatment options and funds:** Funding for fertility services is rarely available in low resource settings, but some components of investigation and treatment may be available as part of general reproductive health promotion programmes. Awareness of the cost of additional treatment and possible sources of funds within the family or community can help couples make informed choices.
7. **Describe best options for tests and treatment:** Knowledge about clinical and cost effectiveness of tests and treatments can help couples in making appropriate decisions.
8. **Educate patients and the public:** Fertility awareness, including prevention, appropriate time for seeking medical help and understanding of the need for fertility services can help overcome some of the existing barriers.
9. **Educate professionals, NGOs and governments:** Awareness and support from service providers and others will substantially improve access to fertility services.
10. **Integrate infertility services with other health services:** Opportunistic use of existing pathways of care offers a cost neutral option for provision of fertility services. Recognize personal and patient barriers to accessing care: Personal cultural, religious and family values that prevent access or limit care need to be recognized and resolved by the untreated infertile, by patients and by care providers.



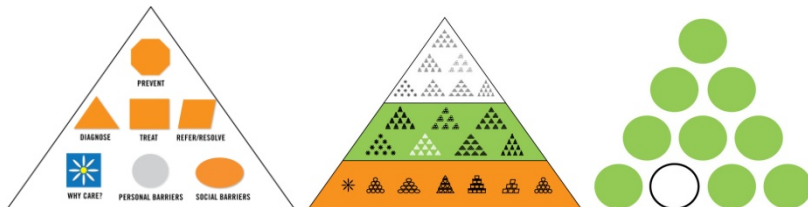
**SUPPORT TOOL 2:
HOW TO OVERCOME PERSONAL AND
PATIENT BARRIERS TO FERTILITY CARE**

Many personal barriers prevent people from getting the health care they need, especially in low resource settings. For infertile women and men, the barriers are even greater than for most health conditions. This tool explains how the individual, health care providers and the infertile can approach personal barriers that prevent access to infertility diagnosis and treatment.



1. Recognize personal and patient barriers to accessing care: Personal cultural, religious and family values that prevent access or limit care need to be recognised and resolved by the untreated infertile, by patients and by care providers.

Infertility is an intensely personal disease/disability which has wide ranging social and cultural implications. Work in a number of different countries has underlined the wide variation in social and psychological consequences of infertility due to cultural and religious influences. The stigma attached to the condition and the gradual erosion of support for a woman in an infertile relationship are genuine obstacles in terms of accessing medical care. The situation is compounded by ignorance and misconceptions about basic reproductive facts both on the part of patients as well as non-specialist and specialist care providers. Religious considerations have also been shown to influence clinical decision making, particularly with regards to assisted conception and use of donor gametes. Recognition of these issues is a fundamental prerequisite of any health seeking behaviour in this context and the literature underlines the role of health education and fertility awareness in this context. (Van Balen and Bos, 2009) Consumer education, self-help groups and other mind-body programs may be helpful in providing support to infertile people. (ASRM, 2012d)

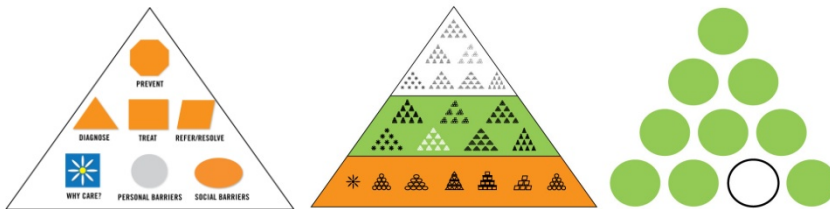


2. Detail cost barriers: The cost of initiating investigations and treatment for infertility is often not covered by available state health services and may require out of pocket payment. This can deter couples from seeking help for infertility.

Spending on health is variable in different parts of the world but in most parts of the developing world the focus of any spending are major infectious diseases such as malaria, tuberculosis and HIV AIDS. Within reproductive health the accent is on maternal mortality, safe abortion and contraception. Fertility treatment is not prioritised partly because of the greater competing demands of more life threatening conditions and due to a perception that the overwhelming need is for fertility control rather than fertility services. Although some

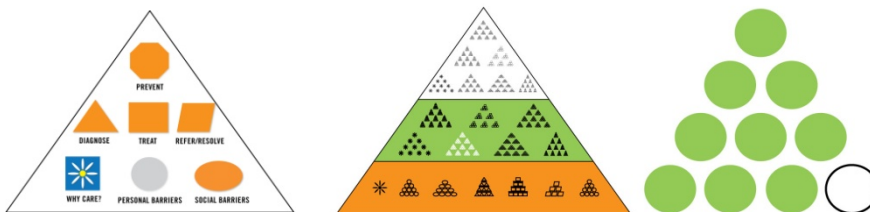
governments provide basic fertility investigations, access to these is patchy and, in the main, fertility services tend to be in the private sector.

As a consequence most couples incur significant out of pocket expenses which, for some, can be catastrophic. Understanding the cost effectiveness of individual tests and treatments for infertility can optimise health gains for couples. Conversely, knowledge that very expensive technology such as IVF may not be affordable may allow them to make informed choices about their reproductive future. (Dyer, 2002)



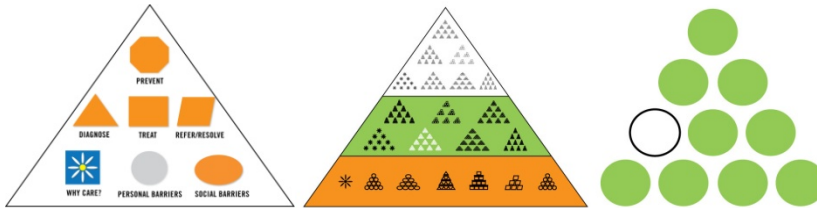
3. Address distance barriers: Geographical factors can influence health seeking behaviour in circumstances where basic infrastructure in terms of roads and transport are suboptimal.

Many couples in the developing world live in countries which lack basic infrastructure in terms of roads, hospitals, equipment and trained staff. Thus there may be few efficient, well equipped and staffed hospitals in primary or secondary care. Thus distance coupled with poor transport systems may prove to be major challenges for couples wishing to access care. While infra structural changes can only be achieved at state level, knowledge of the logistics involved can be helpful to couples wishing treatment. Innovative solutions through using available alternative transport systems can sometimes solve transportation problems for patients. (ESHRE Task Force on Ethics and the Law, 2009)



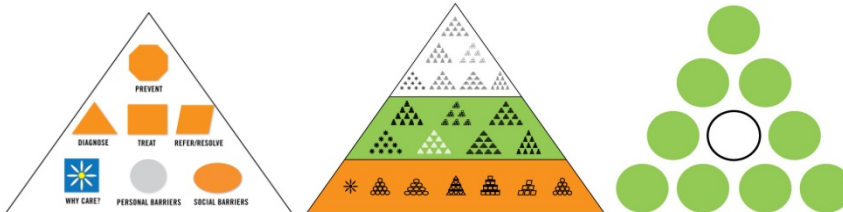
4. Identify family/community barriers: Infertility is regarded in many communities as a personal issue and declaration by couples of their infertile status can lead to stigmatisation.

Social factors have been shown to be strong drivers for fertility treatment, yet couples in most settings see fertility treatment as a very personal event not for public discussion. This can sometimes prevent patients from seeking financial emotional and other support from their families and communities. Efforts to identify specific barriers to health-seeking behaviour for men and women in the context of infertility will enable the development of strategies to overcome these. Knowledge of where men and women turn to for initial advice about infertility will facilitate educational interventions. It is anticipated that this will allow couples to access effective medical treatment at the appropriate time and prevent the use of scarce resources on ineffective remedies. (ESHRE Task Force on Ethics and the Law, 2009)



5. Identify available technology and services: Although assisted reproduction requires sophisticated technology, basic investigations and treatment for infertility may be available in less resource rich settings.

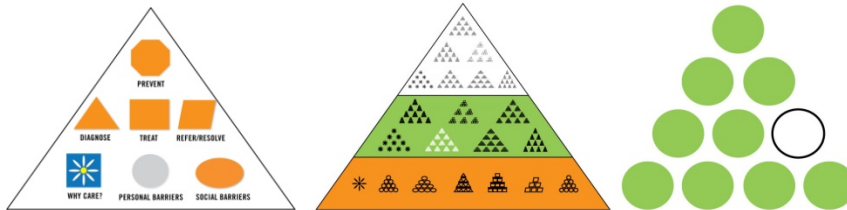
The automatic link between infertility and assisted reproduction has led to stereotypical views on the unaffordability of fertility treatment. In reality, basic investigations such as use of a light microscope for a basic semen analysis, careful history taking to identify anovulation and hysterosalpingogram (HSG) for tubal patency can be made affordable in a number of primary /secondary care settings as the basic infrastructure may already be present. There is ongoing work on identifying ways of addressing common fertility problems using available resources or at minimal extra cost as some of the equipment and staff needed are already present and all that is needed is extra training. (Inhorn, 2009)



6. Identify accessible, affordable treatment options and funds: Funding for fertility services is rarely available in low resource settings, but some components of investigation and treatment may be available as part of general reproductive health promotion programmes. Awareness of the cost of additional treatment and possible sources of funds within the family or community can help couples make informed choices.

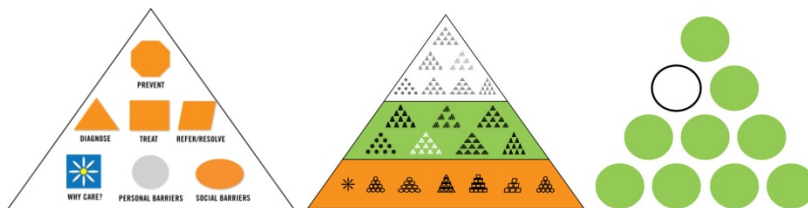
Funding for fertility services per se is often not a priority in developing countries with a number of other pressing health problems. Yet maternal and child health is a key area for most and Millennium Development Goal 5B specifies the need to ensure access to reproductive health care. Basic training and a shift in attitudes among practitioners in primary and secondary care may well enable existing facilities to be used for basic fertility services in a cost neutral manner. Additional investigations and treatment including assisted reproduction may be available in tertiary clinic settings and governments may be persuaded to invest in this sector to reduce health inequalities. Some forms of treatment may require out of pocket expenses and couples should be able to access appropriate information in

order to make informed choices. Ovulation induction, and insemination treatment are examples of relatively low cost solutions to fertility problems.



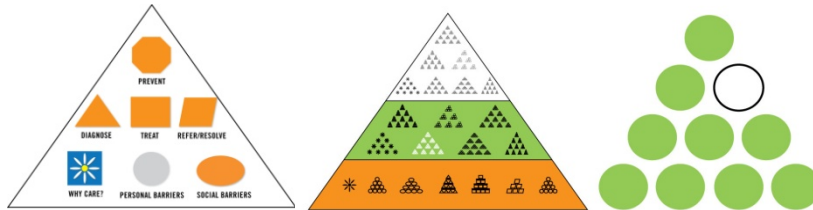
7. Describe best options for tests and treatment: Knowledge about clinical and cost effectiveness of tests and treatments can help couples in making appropriate decisions.

In any clinical setting the focus should be on cost effective investigations and treatment. Over the years availability of technology has been the driver for the introduction of a number of interventions, some of which have yet to be proven to be cost effective. Knowledge of the effectiveness and cost effectiveness of these can help care providers and patients make the right clinical decisions. Existing national and professional society guidelines have identified core tests/treatments, as well as others which are optional, but cost effectiveness of interventions is likely to be influenced by personal and societal values. Patients should have enough information from their providers be able to determine which forms of treatment are unlikely to be helpful.



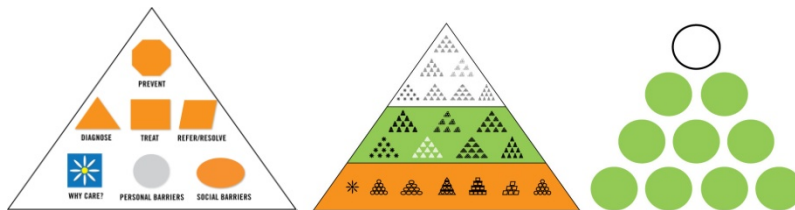
8. Educate patients and the public: Fertility awareness, including prevention, appropriate time for seeking medical help and understanding of the need for fertility services can help overcome some of the existing barriers.

There are major gaps in understanding of the unique nature of fertility problems and the prognosis-based approach to initiating investigations and treatment both among health professionals and the general public. Preventive measures, including avoiding sexually transmitted infections, appropriate timing of reproductive events and avoiding delay in older women, can reduce the risk future subfertility. Correct referral and avoidance of unnecessary investigations can minimise invasive and expensive interventions and contribute towards a more efficient service. Sharing professional information with patients will empower them to have meaningful discussions with clinicians and prevent unnecessary costs in terms of time and finances. (Daniluk, 2012; ASRM, 2012d)



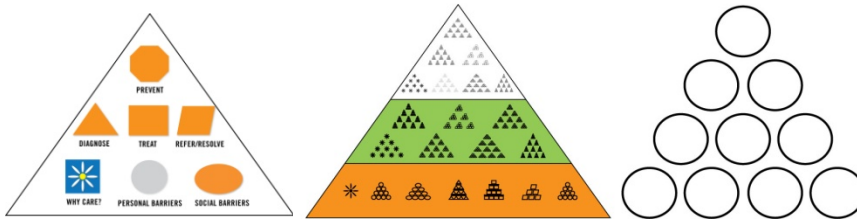
9. Educate professionals, NGOs and governments: Awareness and support from service providers and others will substantially improve access to fertility services.

Knowledge about fertility should be integral to reproductive and sexual health delivery systems. This is important as much of the initial counselling and basic tests and can be accommodated within existing infrastructure and staffing levels. Greater stakeholder knowledge about infertility and effective ways of investigating and treating the condition will facilitate targeted delivery of health care which is effective and affordable. (Ali , 2011)



10. Integrate infertility services with other health services: Opportunistic use of existing pathways of care offers a cost neutral option for provision of fertility services.

Given existing policies of prioritising related elements of reproductive health care such as safe motherhood and fertility control, there is a recognised need to reorganise the existing system of fragmented service delivery systems into a coherent force for improving the health of women. As the basic infrastructure for delivery of maternal child health exists in most countries, there is an opportunity to use existing systems to deliver fertility care with minimal investment in terms of education and a change in attitudes. (ESHRE Task Force, 2008)



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HOW TO OVERCOME PERSONAL/PATIENT BARRIERS TO FERTILITY CARE

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THE FIGO FERTILITY TOOL 3: HOW TO OVERCOME SOCIETAL BARRIERS TO FERTILITY CARE



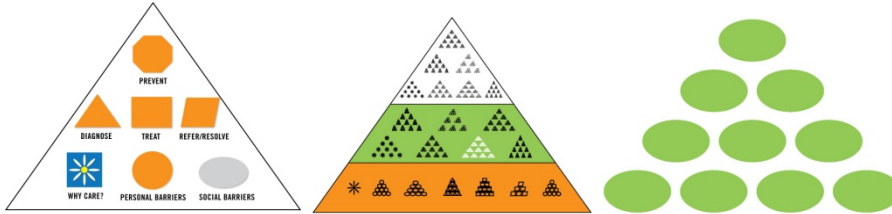
BASIC TOOL 3:

HOW TO OVERCOME SOCIETAL BARRIERS TO FERTILITY CARE

- 1. Identify and reduce socioeconomic, demographic, religious and cultural barriers:** In most countries infertility is not considered a disease and treatment costs must be paid by the individual, usually making them unaffordable and therefore not accessible. Frequently religious and cultural barriers also limit access to care. When these socioeconomic, religious and cultural barriers are identified it is often possible to take some steps to reduce their impact on limiting access to infertility care. Whenever possible, adapt the provision of health care to the best options considering these barriers.

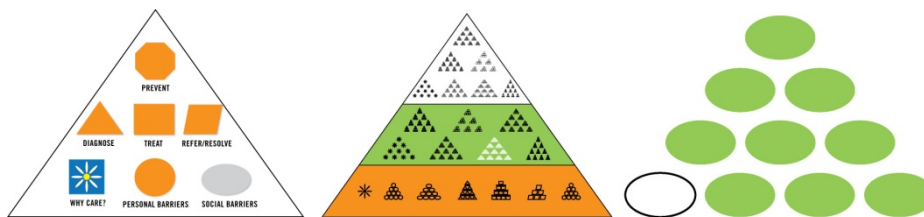
- 2. Identify and manage competition of infertility with other sexual and reproductive health conditions:** Infertility has to compete with other reproductive health problems considered as being more important. Nevertheless, it is usually possible to share physical resources if healthcare personnel can be trained in simple infertility care.
- 3. Identify and improve inadequate health care networks and untrained personnel:** In general, there is little communication between Primary Health Care (PHC) clinics and referring hospitals where infertility is diagnosed and treatments provided. Potential lines of communication from the PHC to Tertiary Health Care (THC) centres and resources should be identified and used to refer patients.
- 4. Identify and improve inadequate infertility risk factor education and insufficient male partner involvement:** The implementation of sex education in schools can reduce the incidence of sexually transmitted infections (STIs) and unwanted pregnancy. Involving males in education and the male partner in infertility treatment can reduce STIs and unwanted pregnancy and improve the quality of family life and the outcomes of fertility treatment.
- 5. Identify Primary Care Providers (PCPs) and Primary Healthcare Clinics (PHC) to develop community educational programs:** PCPs should be trained to educate the community regarding reproductive health and prevention and treatment of infertility, including the role of social factors such as local/religious beliefs and impact of age on fertility. The interconnection of infertility with general health, reproductive health and quality of life should be emphasized.
- 6. Identify infertile couples and develop protocols to transition to appropriate care in the health network, especially between PHC and upper level of care:** Identify those with infertility; and further educate them on the effect of age of the female partner, years of infertility, recurrent gynecologic infection, unsafe termination of pregnancies, and other risk factors. Those with expected normal fertility can be educated and advised to wait in order to avoid unnecessary interventions. Those with identified severe problems should be referred as appropriate.
- 7. Evaluate the psychosocial impact of infertility in the family:** The large impact of infertility on the patient, her partner and their families should be assessed and used to help the patients and other affected/involved individuals.
- 8. Identify organizations that can encourage infertility awareness and influence decision makers:** Since infertility does not constitute a priority in the health agenda of most countries, it is necessary to identify (women) leaders, law makers and others who are sensitive to those suffering from infertility. These organization leaders should be educated about infertility and solutions they could help implement to improve access to quality infertility care.
- 9. Provide training to diagnose and treat low and middle complexity infertility at the PHC setting:** In order to restrict the referrals to only high complexity treatments, it is important to develop the capacity to deal with low or middle complexity treatments at the PHC level by training health providers such as nurses and midwives.
- 10. Strengthen public and private networks to provide high complexity treatments:** Strengthening and cooperation of both public and private networks to bring more cost-effective

simple treatments in the public clinics and less expensive complex treatments in the tertiary care hospitals will enable more patients to access the care they need.



SUPPORT TOOL 3: HOW TO OVERCOME SOCIETAL BARRIERS TO FERTILITY CARE

Many societal barriers prevent people from getting the health care they need, especially in low resource settings. For infertile women and men, the barriers are even greater than for most health conditions. This Tool explains how the individual, health care providers and the infertile can approach societal barriers that prevent access to infertility diagnosis and treatment.



1. Identify and reduce socioeconomic, demographic, religious and cultural barriers: In most countries infertility is not considered a disease and treatment costs must be paid by the individual, usually making them unaffordable and therefore not accessible. Frequently religious and cultural barriers also limit access to care. When these socioeconomic, religious and cultural barriers are identified it is often possible to take some steps to reduce their impact on limiting access to infertility care. Whenever possible, adapt the provision of health care to the best options considering these barriers.

Most people living in low resource situations belong to developing countries with relatively high population growth rates. Thus, infertility is not included as a disease and the costs of treatments need to be paid by individuals rather than society as a whole. Frequently, even the simplest needed services are unaffordable. The inequality in access to reproductive services is equally dramatic for individuals living in low resource settings belonging to emerging economies and/or wealthy countries. (Nachtigall, 2006)

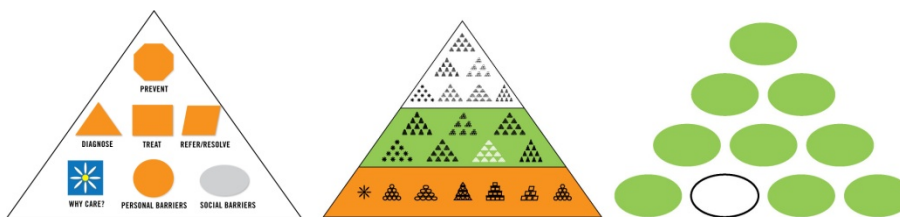
Several ethno-cultural realities constitute a social barrier to access to reproductive health services. High-density populated communities living in extremely low resource environments surround most big cities in developing and developed countries. Many of their inhabitants are native people who have migrated from rural settings, have different dialects and are discriminated against because of their ethnicity. In other cases, people living in peripheral communities have migrated from other countries with different cultures and language. These

ethno-cultural barriers generate isolation, lack of access to social support, and perhaps are the most difficult to incorporate into established social networks.

The influence of religious dogmas can also constitute a barrier to access to reproductive health services. In general, most religions favor big families. However, because of a deistic approach to the understanding of life, very few religions are open to the use of technology when suffering infertility. This is indeed a contradiction to the widespread acceptance of technology to save lives. (Ethics, Bioscience and Life, 2008)

Restrictions imposed by religious mandates not only constitute a barrier for individuals. The influence of some religious organizations can restrict discussion of laws dealing with moral values, specifically those related to human reproduction. In this way, religious perspectives decide what is contained in educational material in schools, and the way laws are discussed and/or applied, often limiting public access to certain fertility treatments.

When these socioeconomic, religious and cultural barriers are identified, it is often possible to take some steps to reduce their impact on limiting access to infertility care. (Ali, 2011; ESHRE Taskforce Ethics & Law, 2009; Ombelet, 2008)

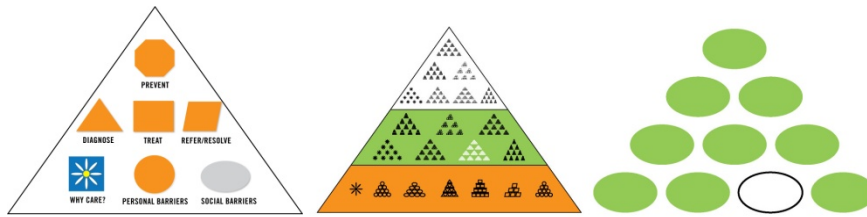


2. Identify and manage competition of infertility with other sexual and reproductive health conditions: Infertility has to compete with other reproductive health problems considered as being more important. Nevertheless, it is usually possible to share physical resources if healthcare personnel can be trained in simple infertility care.

Infertility has to compete with other reproductive health problems considered as having higher priorities such as the prevention of maternal death and childcare, unwanted and adolescent pregnancies, prevention and management of STIs and prevention of cancer. Worldwide, public health strategies for the prevention of death will always find more acceptance than those directed towards the generation of new life, which are interfered with by demographic, social and moral judgments. In this way, economic and human resources required for the management of infertility are postponed when they compete with resources allocated to other health areas considered of higher priority or more importance. (Vayena, 2001)

Although this reality constitutes a serious difficulty for the management of infertility in low resource settings, this barrier is primarily due to lack of trained personnel capable of educating, providing counseling and managing infertility. Overall, most of the facilities and equipment used for maternal care, prevention of sexually transmitted infections (STIs) and cancer, can be efficiently shared in the diagnosis and treatment of multiple causes of infertility. It is the time allocation of human resources that is the most difficult challenge. This problem can be overcome by the training of nurses, midwives and other mid-level providers in simple infertility

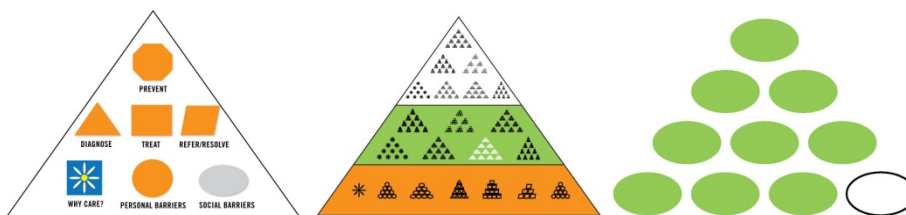
management care that can be integrated into other women’s healthcare programs. (Zegers-Hochschild, 2011)



3. Identify and improve inadequate health care networks and untrained personnel: In general, there is little communication between Primary Health Care (PHC) clinics and referring hospitals where infertility is diagnosed and treatments provided. Potential lines of communication from the PHC to Tertiary Health Care (THC) centres and resources should be identified and used to refer patients.

It is very difficult for infertile couples to move from a PHC system devoid of appropriate equipment and trained personnel but located in their vicinity, to a THC system with few infertility specialists, often inaccessible, and having to wait for weeks or months before medical attention is provided. Furthermore, most of the time there are no protocols for the transfer of patients from one level to the next. This reality is especially difficult to overcome by infertile couples living in rural communities with no public transportation and where PHC clinics are geographically isolated from health centers with trained personnel.

It is possible for mid-level providers to identify the potential lines of communication from their PHC to the THC, both on a clinical basis and on a business/organizational basis. Attention must be paid to the realities of local politics, economics and personalities. Simple solutions that help improve the situation of all those involved are important. Small steps that have initial success are more important than larger, longer-term approaches, at least at the beginning. Enlisting the help of others who share similar views and goals can help ensure success. (Zegers-Hochschild, 2011)

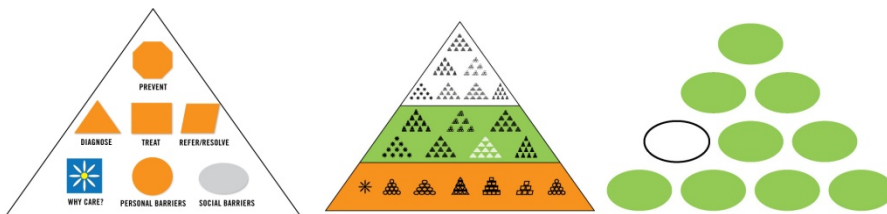


4. Identify and improve inadequate infertility risk factor education and insufficient male partner involvement: The implementation of sex education in schools can reduce the incidence of sexually transmitted infections (STIs) and unwanted pregnancy. Involving males in education and the male partner in infertility treatment can reduce STIs and unwanted pregnancy and improve the quality of life and outcomes of fertility treatment.

Lack of sexual education in schools and the early initiation of sexual activity increase the risks of sexually transmitted diseases and other conditions, some of which may affect fertility. This,

together with a postponement of maternity in urban communities, contributes to both reduced fertility and increased exposure to risk factors. In the absence of education in schools, the PHC clinic should provide mothers with tools to educate their children on how to prevent unwanted pregnancies and STIs.

An additional problem is that in many communities it is difficult to involve husbands in the management of infertility; this is often due to the popular belief that fertility is associated with masculinity and femininity. In some cultures and ethnic groups the responsibility of the male partner in reproduction is not recognized, and it is therefore difficult, if not impossible, to gain their participation in diagnostic or therapeutic procedures. The involvement of the husband may also be seen as weakness. This may result in his not allowing his wife to disclose their infertility or simply obtaining another wife in polygamous societies. Efforts should be made to facilitate the collection and examination of semen sample in accordance with cultural and religious values. Discussions with religious or other leaders that can identify acceptable behaviors for both men and women to facilitate fertility diagnosis and treatment should be undertaken by PCPs.

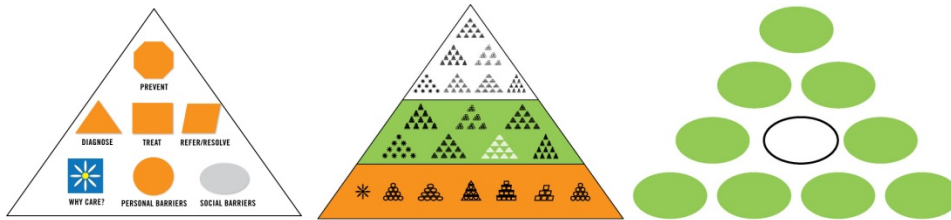


5. Identify Primary Care Providers (PCP) and Primary Health Care (PHC) clinics to develop community educational programs: PCPs should be trained to educate the community regarding reproductive health and prevention and treatment of infertility, including the role of social factors such as local/religious beliefs and impact of age on fertility. The interconnection of infertility with general health, reproductive health and quality of life should be emphasized. In order to overcome some of the barriers described previously, there are three activities to be undertaken at PHC level.

Health providers, ideally midwives, should be motivated and eventually trained to develop workshops and community programs oriented towards the prevention of reproductive health problems, including the prevention and treatment of infertility. The role of social factors such as local cultural/religious beliefs and social attitudes that can influence fertility as well as other reproductive health diseases should be identified and discussed with the public. The community should also be educated on the effect of age and years of infertility as prognostic factors for infertility.

Educational curricula for the prevention of infertility should be accompanied with education in other areas of reproductive health such as fertility regulation, STIs, the prevention of cancer and the impact of good reproductive health on the quality of life.

Ideally, the PHC facility should become the place where the community meets, where women can discuss their problems and health education is provided. It is essential to identify community leaders to work hand in hand with the nurse/midwife so that together they are capable of gathering consumers around the PHC facility. (Zegers-Hochschild, 2011)

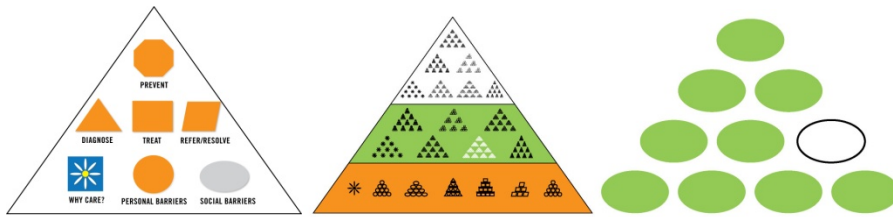


6. Identify the infertile and develop protocols to transition to appropriate care in the health network, especially between PHC and upper level of care: Identify those with infertility; and further educate them on the effect of age of the female partner, years of infertility, recurrent gynecologic infection, unsafe termination of pregnancies, and other risk factors. Those with expected normal fertility can be educated and advised to wait in order to avoid unnecessary interventions. Those with identified severe problems should be referred as appropriate.

Identify those with infertility so that they can receive appropriate diagnosis, treatment and support. Educate patients further on the effect of age of the female partner, years of infertility, recurrent gynecologic infections, unsafe pregnancy termination, and other factors, which can jeopardize the success rate of any form of therapy. It is also at this level that normal couples can be educated, including about non-intervention methods that optimize natural conception and pregnancy outcome, and advised to wait in order to avoid meddlesome and unnecessary interventions.

In the absence of trained personnel, infertile couples need to be referred to higher levels of care where infertility specialists can provide further counseling and/or specific treatments. In general, this transition is difficult due to lack of protocols for the transfer of patients. Furthermore, trained professionals are frequently lacking in the referral center or have long waiting lists. These conditions must be identified at the PHC in order to avoid unrealistic expectations and the suffering that results from inefficient transfer of patients from one place to the other seeking medical treatment.

The most important action at this level is to build up a network of institutions capable of dealing with infertile patients in the most efficient way. Then, the PCP should work together with the government health organization representatives (Ministry of Health or equivalent) to develop and implement protocols for the efficient transfer of infertile patients to facilities where they can receive appropriate treatments.



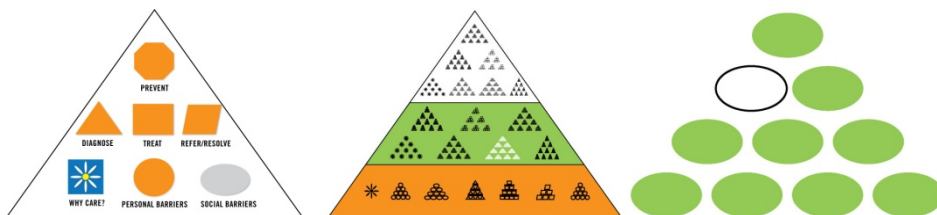
7. Evaluate the psychosocial impact of infertility in the family: The large impact of infertility on the patient, her partner and their families should be assessed and used to help the patients and others who are affected/involved.

The psychosocial impact of infertility on the affected people and their families is usually very significant. The healthcare provider can subjectively assess by simple questions to the patient and her partner the effect on her personal life, married life and within her family.

More objective assessments can be measured through self-applied questionnaires, such as FertiQol, or others. (Boivin, 2011) Assessment by mental health professionals, when available, can provide additional insight and support for the patient.

The information obtained can be used to counsel the individual patient, her partner and, when possible, their families. Research can be done with these results to better understand the impact of infertility in different settings.

Non-identifying information obtained from these questionnaires should also be used to influence authorities on the need of care for infertile couples.

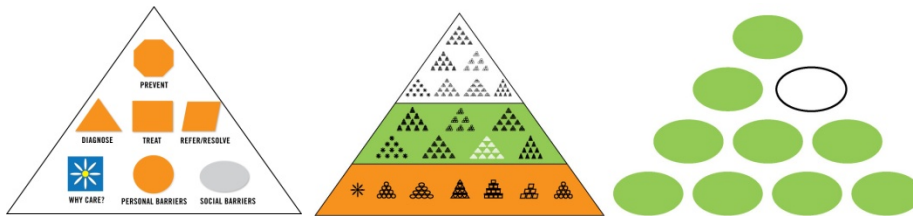


8. Identify organizations that can encourage infertility awareness and influence decision makers: Since infertility does not constitute a priority in the health agenda of most countries, it is necessary to identify (women) leaders, law makers and others who are sensitive to those suffering from infertility. These organization leaders should be educated about infertility and solutions they could help implement to improve access to quality infertility care.

Infertility does not constitute a priority in the health agenda of many countries, and especially developing countries.

This is partly because most poor countries have high population growth rates and, therefore, those suffering from it, devoid of public support, experience infertility in complete isolation.

In order to get attention from public authorities, different strategies can be undertaken: (1) identify (women) leaders with the capacity to bring infertile patients together in groups or organizations whose goal is to defend the reproductive right to access modern, efficient and safe medical treatments; (2) identify law makers and other authorities who are sensitive to those suffering from infertility and will work to improve access to infertility care, and ; (3) educate organizational and government leaders on the burden of infertility for individuals and their families, provide them with accurate information on the magnitude and impact of the problem, and suggest alternative approaches that help those with infertility have increased access to quality infertility care.



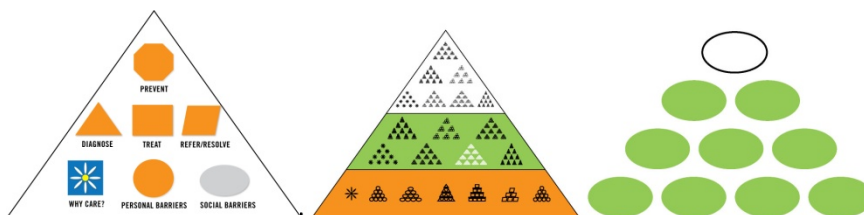
9. Provide training to diagnose and treat low and middle complexity infertility at the PHC setting: In order to restrict the referrals to only high complexity treatments, it is important to develop the capacity to deal with low and middle complexity treatments at the PHC level by training nurses and midwives.

Nurses and/or midwives must be trained in order to deal with specific diagnostic categories and treatments in the PHC setting.

Training should include, among other things, the reasons for treating infertility, the psychological characteristics and impact of infertility, the elements of both a screening and detailed reproductive history and a physical examination that will identify potential infertility findings.

The nurse and/or midwife should be trained to perform transvaginal ultrasound, monitor controlled ovarian stimulation with clomiphene and possibly gonadotropins, and identify complications of treatment.

The nurse and/or midwife should eventually serve as a bridge between the PHC and the referral hospital where many patients might need referral.



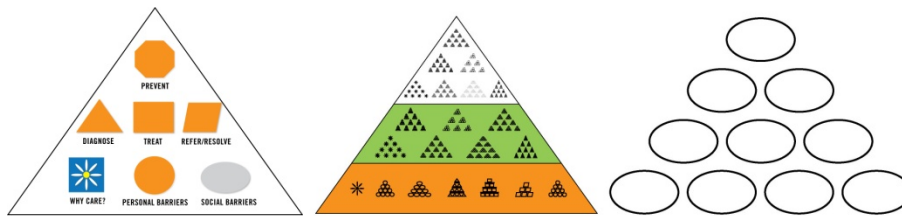
10. Strengthen public and private networks to provide high complexity treatments: Strengthening and cooperation of both public and private networks to bring more cost-effective

simple treatments in the public clinics and less expensive complex treatments in the tertiary care hospitals will enable more patients to access the care they need.

In most, and especially developing, countries there are many significant socioeconomic disparities. Few people have access to private institutions providing high complexity infertility treatments and the vast majority of citizens have limited access, restricted to hospitals belonging to the public sector with limited infrastructure.

It is indeed difficult to level this inequality, but strategies should include both decreasing the costs of complex medical treatments and establishing some sort of partnership between private and public institutions.

Working under the umbrella of a recognized public health authority, these partnerships should focus on partial subsidies to the cost of treatments and on additional strategies and programs that increase access and affordability to quality infertility treatment.



REFERENCE TOOL 3: HOW TO OVERCOME SOCIETAL BARRIERS TO FERTILITY CARE

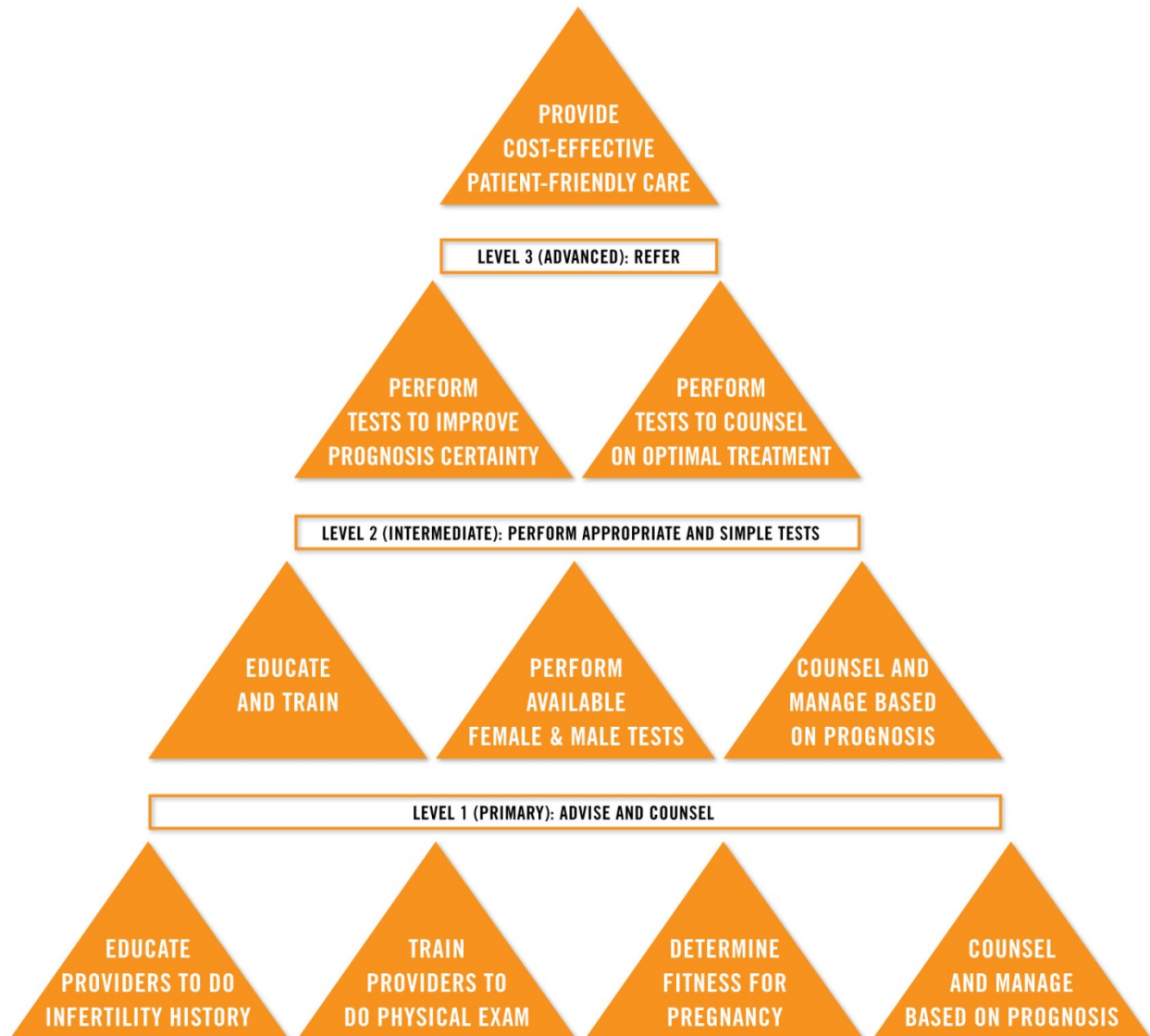
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Tools

Levels

Actions

THE FIGO FERTILITY TOOL 4: HOW TO DIAGNOSIS INFERTILITY



BASIC TOOL 4: HOW TO DIAGNOSE INFERTILITY

Levels of Infertility Care and Services

The toolbox for diagnosis describes care at three levels from lowest resources/personnel/cost at the bottom of the pyramid to highest at the top.

Level 1 or Primary Care level services: Advise and counsel

- 1. Educate the Primary Care Provider (PCP) on infertility history:** Teach the PCP to take a simple infertility history by asking questions on the age of both partners, duration of infertility, primary/secondary infertility, obstetrical history, coital practices and factors predisposing to tubal damage.
- 2. Train the PCP to do a physician examination:** Where possible, teach the PCP to inspect the vagina and cervix and to do a bimanual examination to find out whether it is painful, there are adnexal masses and the uterus is enlarged.
- 3. Determine the patient's fitness for pregnancy; focus on co-morbidity:** The PCP has to assess whether the infertile woman is fit for an eventual pregnancy and focus on the presence of co-morbidity.
- 4. Counsel and manage the patient:** Counsel and manage the patient, including optimizing natural fertility, advising on lifestyle and health, determining the prognosis for live birth and referring the patient(s) to a higher level of care if possible and appropriate.

Level 2 or Intermediate Care level services: Perform appropriate and simple tests

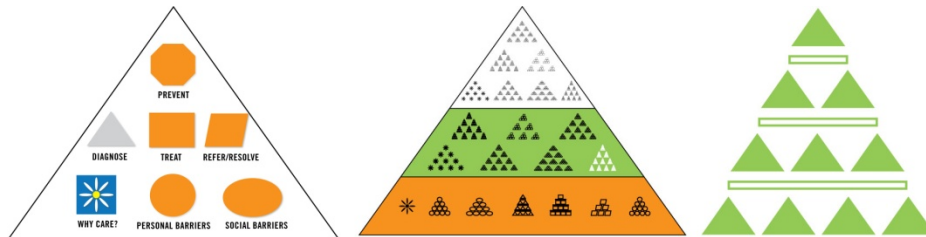
- 1. Educate and train as in level 1.1 and 1.2:** Education and training in the basics of infertility are required at all levels of infertility diagnosis.
- 2. Perform available female and male tests with the aim to exclude tubal pathology and severe male infertility:** Both female and male partners should be tested. Appropriate tests that are available should be used. The goal is to exclude significant problems that can prevent or severely limit the chance of pregnancy, especially tubal damage and severe male infertility.
- 3. Counsel and manage the patient:** See Level 1.4. It is necessary to counsel and manage the patient(s) at all levels, and especially after test results are obtained that can change the understanding of the problem, the chances for pregnancy and/or the treatment that will be appropriate and possible.

Level 3 or Advanced Care level services: Refer

- 1. Perform additional tests to improve quality of prognosis:** The results of Primary Care and/or Intermediate Care tests may suggest that additional tests might help in confirming the diagnosis and/or different diagnoses.
- 2. Perform female and male tests to decide and counsel on optimal treatment:** Where possible, all effective, cost-appropriate tests that can improve the diagnosis AND prognosis in a clinically meaningful way should be performed if available. The patient(s) should be counseled regarding the test results and their impact on the treatment options that are reasonable for the patient(s) to consider.

Level 4. Aspirational Goal of Diagnostic Tests

- 1. The ultimate goal is to apply cost-effective and patient-friendly care at each level:** Cost-effective care will achieve a diagnosis that leads to the most accurate prognosis and understanding of the most appropriate treatment options in a manner that is supportive of the patient and provides the optimal chances of resolving the infertility disease/disability.



SUPPORT TOOL 4: HOW TO DIAGNOSE INFERTILITY

From a diagnostic to a prognostic approach

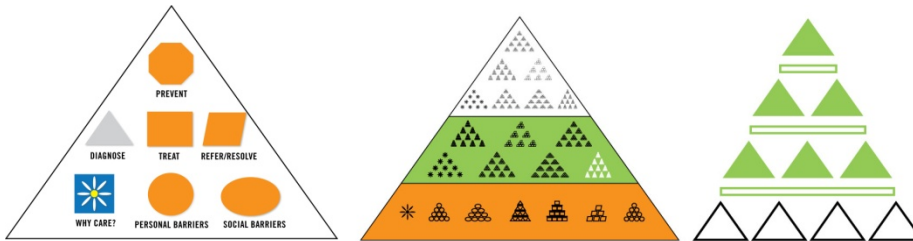
The principle from general medicine ‘first establish a causal diagnosis and then apply the appropriate treatment’ only applies for clear-cut conditions like anovulation, bilateral tubal disease and severe male infertility in reproductive medicine--disorders with almost zero chances of a natural conception requiring immediate treatment.

However, most types of infertility are not clearly attributable to a specific cause and are classified into ambiguous, vague, sometimes debatable diagnostic categories such as unexplained infertility, mild endometriosis, cervical factor infertility and mild/moderate male factor infertility. (Evers, 2002) Moreover, as infertility applies to a couple of a female and male individual, there is often more than one diagnostic category related to the cause of infertility. The tests on which these categories are based do not reliably distinguish among fertile, subfertile and infertile couples (Guczik, 1994); their natural pregnancy chances may vary from almost zero to almost normal. The management of such couples mainly depends on whether the couple should still wait for a spontaneous pregnancy or should be treated now. Once tubal disease, anovulation and severe male infertility have been excluded, some simple information from the previous history and a few diagnostic tests are sufficient to determine a reliable estimate for the occurrence of spontaneous pregnancy. (Hunault, 2004; Van der Steeg, 2007)

The age of the female partner, the duration of the infertile period and whether the infertility is primary or secondary are the most important factors. The results of a simple sperm quality test and/or a well-timed post coital test improve the prognostic performance. From these data a prognostic index and the corresponding probability to conceive spontaneously within the following year can be derived. (Hunault, 2004) Therefore, in the diagnostic tool we move from the traditional diagnostic approach to a simpler, less costly and more effective prognostic approach.

The hierarchy levels

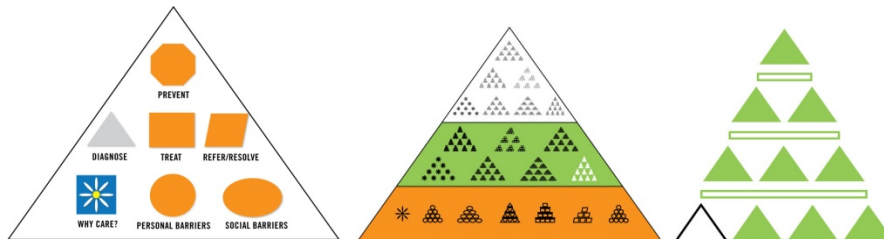
The hierarchy of this pyramid tool goes from a primary care level 1 with no diagnostic possibilities whatsoever to an intermediate care level 2 with some diagnostic options to an advanced care level 3 where all sophisticated diagnostic tools and tests are available. We aim this diagnostic scheme to be cost-effective and patient-friendly at all levels of care, and therefore position this as an aspirational goal on top of the pyramid.



Level 1 or Primary Care level services: Advise and counsel

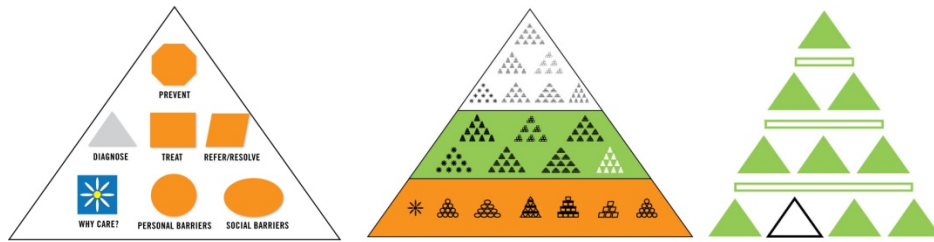
The setting is usually a simple primary health center/clinic (PHC) run by a midwife and/or staff nurse as PCP or Health Provider (HP) without any diagnostic or therapeutic possibilities. The PCP is primarily busy with deliveries and pre- and perinatal care. She may be also involved in family planning, under several clinics with vaccination programs, and prevention of STI and HIV; undertakings which are also important for the prevention of infertility and childlessness (See Prevention Tool 7). It is often possible and easily doable to combine infertility care with these other medical activities.

What can be done in Level 1 by Primary Care Providers?



- 1. Educate the PCP on infertility history:** Teach the PCP to take a simple infertility history by asking questions on the age of both partners, duration of infertility, primary/secondary infertility, obstetrical history and factors predisposing to tubal damage.

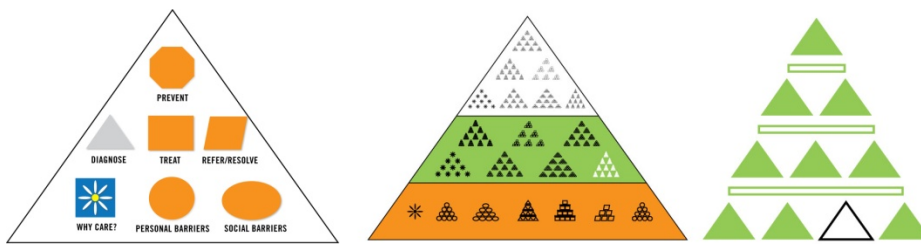
Details regarding past pelvic infection, fever after delivery, elective abortion, pregnancy loss and STIs should be obtained. Coital practices and knowledge of the fertile period should be determined. The socioeconomic status should be asked. It is important to know if there is a pattern of regular cycle bleeding about once per month. Teach the PCP why these questions are important and how they can be used for a pregnancy prognosis. (See 4 below) (ASRM Practice Guidelines, 2012; ACOG and ASRM, 2008; ASRM, 2012c)



2. Train providers to do a physical exam.

Where possible, teach the PCP to inspect the vagina and cervix for discharge and to do a bimanual examination. Is there abnormal tenderness, are there adnexal masses, is the uterus enlarged, is there restricted mobility of the pelvic organs?

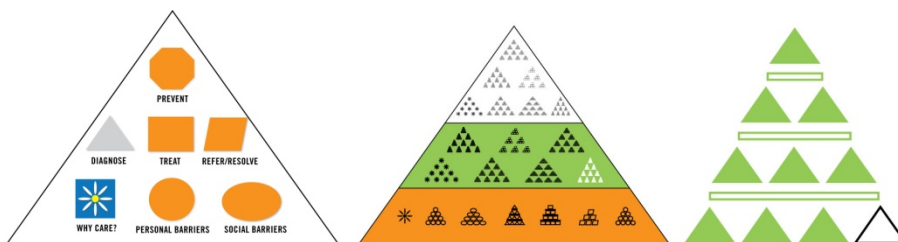
Teaching pelvic bimanual examination can be difficult for cultural, educational, clinical and other reasons. Nevertheless, health care providers should be taught these skills where possible. While difficult, pelvic examination can sometimes aid significantly in the diagnosis. (ASRM,2006a;ASRM, 2008f)



3. Determine fitness for pregnancy and identify co-morbidity.

Determine whether the woman is fit for a pregnancy. Is she malnourished, underweight, overweight or anemic? Determine the hemoglobin and test the urine on sugar or infections. Focus on co-morbidity such as malaria or a chronic infection. Is there an increased risk of HIV?

Co-morbidities can often be determined by simple history and physical examination, yet can have a profound effect on the outcome of pregnancy. Co-morbidities should be treated/managed as effectively as possible to optimize the chances for conception and a healthy pregnancy. (ASRM, 2008a; ASRM, 2008e)



4. Counsel and manage the patient

a. Optimize natural fertility. (ASRM, 2008a; Stanford et al 2010)

Try to convince the couple not to give up and keep up a coital frequency of at least twice a week, even after years of infertility and certainly during the fertile period. (For example, a reduction in the average frequency of intercourse from twice to once a week results in a 40% reduction in probability of pregnancy per cycle. (Stanford and Dunson, 2007) Teach her to determine the most fertile period by examining her cervical mucus. (Scarpa et al, 2006)

b. Advise on the importance of lifestyle and health

Smoking, alcohol use and possibly excessive caffeine decrease the likelihood of spontaneous conception. (ASRM, 2008m) Lubricants or vaginal douching may have a detrimental effect on sperm vitality. Overweight women have a decreased chance of conceiving, even when having a regular ovulatory cycles. Moderate weight loss increases this chance. (van der Steeg et al, 2008) Above age 30 the likelihood of live birth conception progressively decreases. (te Velde and Pearson, 2002). The best, most healthy diet possible should be discussed and recommendations made.

c. Determine the prognosis for live birth

With the information collected even in a PCP setting, it is possible to give at least an approximate prediction of the chance of achieving a pregnancy and live birth (LB) during the following year, provided the woman has regular cycles, regular unprotected intercourse, open tubes and a male partner who has at least some living sperm cells. At this level we do not know whether these conditions are met, but the history and results of pelvic examination give important clues. In case of a more or less regular monthly menstruation pattern, the cycle most likely is ovulatory. Women with secondary infertility (especially if longstanding), various sexual partners, pelvic infections and infections after delivery/abortions, abundant vaginal discharge and/or tenderness during bimanual palpation, have an increased likelihood of tubal pathology. (ASRM, The biggest 'predictor' for tubal infertility is the absence of another fertility factor. (Dyer 2011, personal communication)

With regard to sperm quality: azoospermia is rare; the vast majority of male partners is expected to have at least some vital sperm cells in their ejaculate. This is almost 100% certain when the infertility is secondary.

Accept the considerable level of uncertainty of the estimate: it is often the best that can be done in low resource settings or circumstances in which there is limited or no diagnostic testing possible.

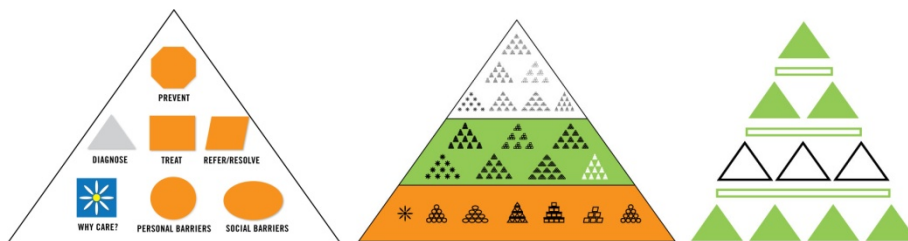
The major factors that predict a better prognosis are young age of the female (< 30 years), short duration of infertility (< 2 years), absence of evidence of tubal disease, and normal semen analysis.

Why is it useful to know the chance of live birth conception when there are no appropriate treatment possibilities available?

Women often underestimate their chances to conceive spontaneously if no pregnancy ensues after half a year or one 1 year of trying. They often assume by that time they are sterile and will never have a child. This is understandable when taking into account the fact that most of their acquaintances trying to conceive have been successful within that period. Therefore, they are inclined to give up or demand some far-away and expensive treatment. The PCP should tell the couple that primary sterility is relatively rare. Recent estimates of the truly sterile fraction of couples wishing to have children vary by age, from 1% at 25 years, 2% at 30 to 5% at 35 and 17% at age 40. (Leridon, 2008) Even after 1 year of infertility there is a considerable chance of conceiving spontaneously and having a live born pregnancy within the following year or two— a much higher chance than most couples and doctors realize, (te Velde, 2000; Habbema, 2009; Dunson, 2004; van Balen,1997; Tietze, 1950; Stanford, 2010). It is very important to encourage the couple to continue trying every month and not to give up or become desperate.

d. Refer the couple to Level 2 (Intermediate Care) or Level 3 (Advanced Care) if possible and appropriate.

Especially when referring the couple to Level 3 where treatment almost always has to be paid out of pocket, it is important to consider the socioeconomic status of the couple: can they afford to pay the treatment or will such expenses be “catastrophic” for their future expenses. (Xu,2003)



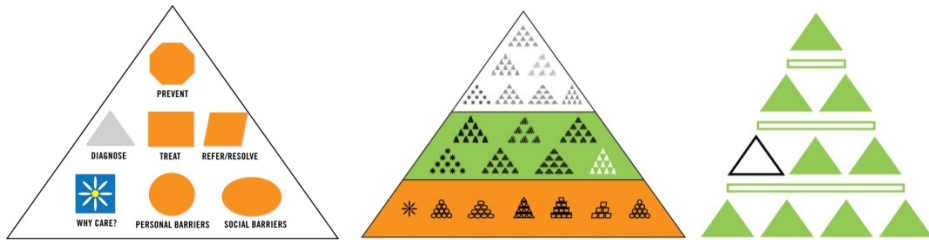
Level 2 or Intermediate Care level services (every level between level 1 and level 3): Perform appropriate and simple tests

The setting of this level may vary enormously: it may be a Reproductive Health Clinic (RHC) or a simple secondary hospital where only simple sperm examination or inspection of the cervical mucus for sperm cells (Post Coital Test) are possible. In a secondary hospital an X-ray service may be present in which a hysterosalpingogram (HSG) can be performed. There may be a medical doctor who can remove an adnexal mass, handle an ectopic pregnancy or perform some simple fertility surgery. The infrastructure of the RHC/secondary hospital may contain a good microscope and a technician who is able to perform a proper semen analysis. Sometimes ultrasound equipment with a transvaginal probe may be available as well as personnel able to perform and interpret ultrasound examination of the pelvic organs.

What can be done in Level 2 or Intermediate Care level services?

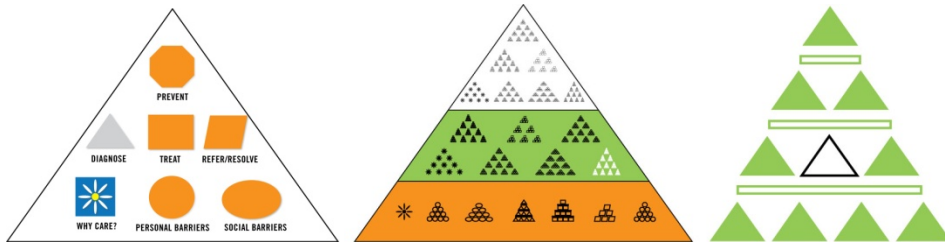
What can be done in Level 2 or Intermediate Care is similar to the options in Level 1 or Primary Care, but with the added benefit of the availability of some diagnostic tests that allow for a more reliable prognostic assessment. Moreover, some simple treatments like ovulation

induction with clomiphene citrate, simple tubal surgery and intrauterine insemination (IUI) can be applied (See Treatment Tool 5).



1. Educate and train as in level 1.1 and 1.2: Although more knowledge and know-how are likely to be available at this level, teaching and training on taking an appropriate infertility history and to do physical exam often remain necessary at level 2 (See Level 1).

Education and training in the basics of infertility are required at all levels of infertility diagnosis.



2. Perform available female and male tests with the aim to exclude tubal pathology and severe male infertility: Both female and male partners should be tested. Appropriate tests that are available should be used. The goal is to exclude significant problems that can prevent or severely limit the chance of pregnancy, especially tubal damage and severe male infertility. (ASRM, 2012c)

a. Tests excluding, diagnosing or suspecting tubal pathology.

Perform HSG with antibiotic prophylaxis. Use oil-soluble contrast: there is evidence-based support for a therapeutic effect (Luttjebroer, 2007) in contrast to water-soluble contrast (Lindgren, 2009).

Determine the Chlamydia antibody titer when there is a possibility to send a serum sample of the woman to a laboratory. If the titer is high tubal pathology is strongly suspected. (Mol , 1997; ASRM and SRS, 2008b)

b. Semen analysis

The possibility of performing a semen analysis may vary greatly in different settings. At one end of the spectrum there may be a simple microscope with a PCP who is able to differentiate between the presence of sperm or no sperm, and if present between moving and not moving sperm. Even this limited knowledge can be very useful.

In another setting there may be a good microscope and a technician who is able to perform a semen analysis according to the latest WHO recommendations. (World Health Organization, 2010)

c. Post coital test (PCT)

The PCT is a controversial test. Part of the confusion is caused by the fact that it is used as a diagnostic test to detect so-called “cervical hostility” and immunological-related subfertility in order to decide on appropriate treatment, but it is also used as a prognostic test. The results of the PCT as a diagnostic test are disappointing. (Griffith and Grimes, 1990; Oei et al, 1998) In contrast, the performance of the PCT as a prognostic test to predict spontaneous pregnancy is rather good; especially a positive test result is strongly correlated to the occurrence of a spontaneous pregnancy. (Hull, 1982; Eimers, 1994; Snick, 1997).

In circumstances in which male partners find it difficult or embarrassing to produce a sample for sperm testing – as is the case in many parts of the world - the PCT is a reasonable alternative for a sperm analysis or gives additional information. (Hunault, 2004)

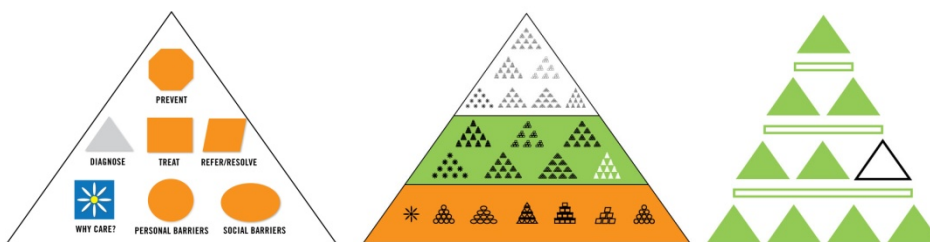
The technical performance of a PCT is relatively simple and only requires the availability of a microscope. However, other factors can make performance of the test more difficult. If the patient has difficulty traveling to the health facilities, especially on short notice, or if the PCP cannot see the patient without an appointment or has other limitations, it is important to try to identify solutions to these problems. The woman has to be instructed about timing intercourse just before ovulation. Intercourse should occur the previous evening or during the night or early morning; the patient comes in for the test in the morning after intercourse because this gives the most useful information for prognosis.

The PCP has to collect some mucus from the cervical os (opening) and look for the presence or absence of (moving) sperm cells under the microscope. One or more actively moving sperm is considered a normal test result. If well-timed, repeating the test is not necessary.

d. Ultrasound with vaginal probe

If an ultrasound with a vaginal probe is available and the PCP or physician has ultrasound expertise not only to perform but also to interpret results, the following conditions may be diagnosed or suspected: ovulatory (dys)function, ovarian cysts, solid/mixed ovarian tumor, endometrial polyp, submucosal fibroid, presumed presence of tubal pathology or endometriosis. (ASRM, 2006a; ASRM, 2008f; ASRM and SRS, 2008a; ASRM and SRS, 2008b)

With such diagnostic expertise, the PCP/physician is better able to do simple treatments at the PHC. (See Treatment Tool)

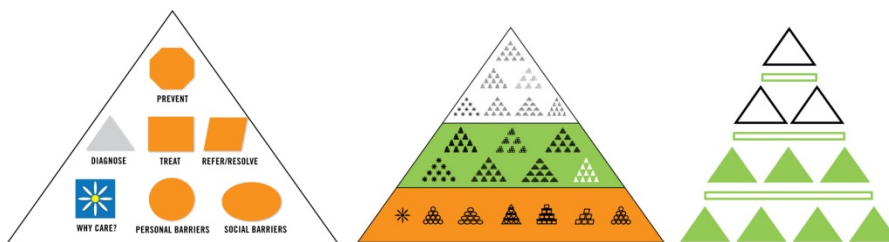


3. Counsel and manage the patient: See Level 1.4. It is necessary to counsel and manage the patient(s) at all levels, and especially after test results are obtained that can change the understanding of the disease/disability, the chances for pregnancy and/or the treatment that will be appropriate and possible. The passage of time and results of treatments will change the prognosis and the counseling and management needed by the patient.

In principle, counseling and management are the same as in Level 1: optimize natural fertility, advise on the importance of lifestyle and health, determine prognosis for live birth and refer the couple to Level 3 Advanced Care if possible and appropriate. (ASRM, 2008a)

Because more diagnostic information is available – severe male infertility and bilateral tubal obstruction can be excluded - the degree of uncertainty about the prediction is less than in Level 1. Moreover, the available diagnostic options also allow initiating and monitoring simple forms of treatment.

The major factors that predict a better prognosis are young age of the female (< 30 years), short duration of infertility (< 2 years), absence of evidence of tubal disease, and normal semen analysis.

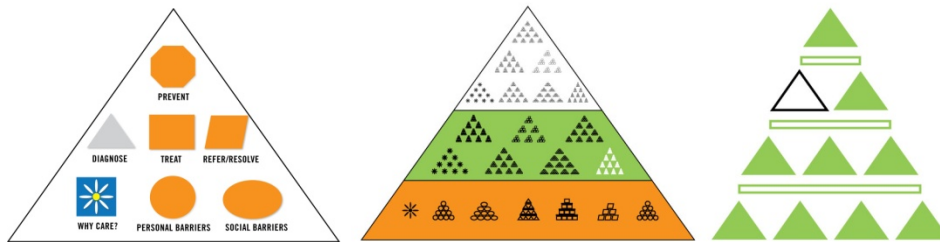


Level 3 or Advanced Care level services: Refer

The top Level 3 Advanced Care is a tertiary hospital which sometimes has all the diagnostic and therapeutic facilities as in referral hospitals in developed countries.

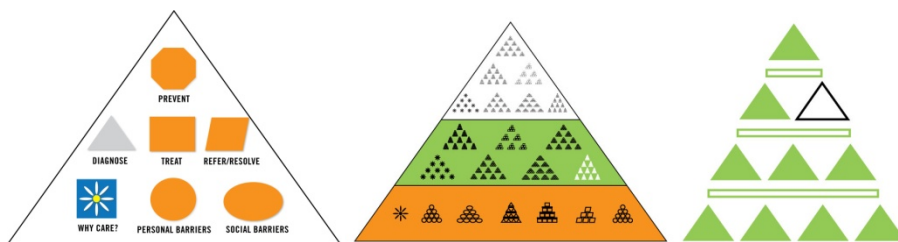
The diagnostic possibilities at this level include hormonal assessment of pituitary, ovarian, adrenal and thyroid function and the interplay among these organs, e.g. the pituitary-ovarian axis. Sophisticated ultrasonography enables diagnosis of subtle intrauterine, ovarian and abdominal pathology. Magnetic resonance imaging (MRI) services permit diagnosing pituitary, adrenal and ovarian pathology. Genetic tests estimate genetic risks and permit counseling of couples accordingly. Laparoscopic expertise tests the patency of both tubes and can detect subtle abnormalities related to adhesions, endometriosis and tumors. A reproductive surgeon can judge whether operating to diagnose and treat these conditions is worthwhile. (ASRM, 2008d; ASRM, 2008k; ASRM, 2008l; ASRM, 2012a; ASRM 2012c; ASRM and SMRU, 2008)

What can be done in Level 3 or Advanced Care level services?



1. Perform additional tests to increase the level of certainty of the prognosis.

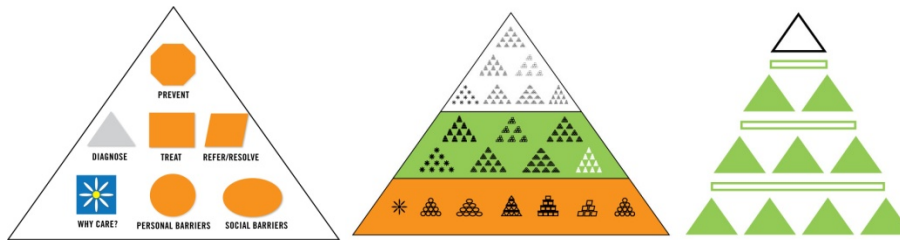
- a. Exclude tubal pathology by performing laparoscopy in addition to HSG – if the result of HSG is ambiguous.
- b. Do cycle monitoring by ultrasonography and hormonal testing if in doubt about the presence of ovulation.
- c. Perform 1 or 2 semen analyses according to WHO guidelines (WHO, 2010) if in doubt about sperm quality.



2. Perform appropriate female/male tests to decide on optimal treatment.

Treatment has to be applied without delay in the case of tubal pathology, anovulation and severe male infertility. If the period of expectant management was unsuccessful, appropriate treatment has to be applied. Whether and which diagnostic tests are to be performed can only be judged in the light of the available evidence-linked treatment options (See Treatment Tool).

Sophisticated diagnostic tests for ovarian status include complete endocrinology evaluation, pelvic imaging tests, hysteroscopy, laparoscopy, and also male tests, some of which could be invasive such as testicular biopsy. (ASRM 2012c; ASRM and SMRU, 2008)

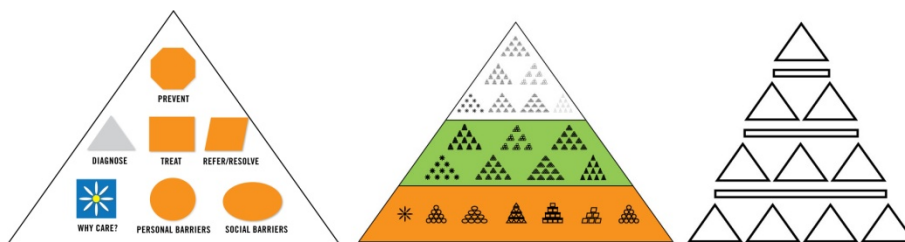


3. Provide cost-effective, patient friendly care

We aim this diagnostic scheme to be cost-effective and patient-friendly at all levels of care, and therefore position this as an aspirational goal on top of the pyramid.

This is important because resources are limited in all countries of the world, even developed countries. Additionally, as a matter of principle, resources should not be wasted.

Furthermore, except in optimal situations, only approximately half of all infertility patients will have a child as a result of treatment. In most low resource settings the likelihood of an infertile patient taking home a baby is almost certainly less than this. Therefore, it is critical not to waste patients' personal resources, and to treat them with dignity, respect and friendliness at all times so that the time spent, financial costs, physical risks and emotional toll of infertility is minimized to the extent possible. This is why the best possible diagnosis that can result in the best possible accuracy of the prognosis is so important early in the management of the patient.



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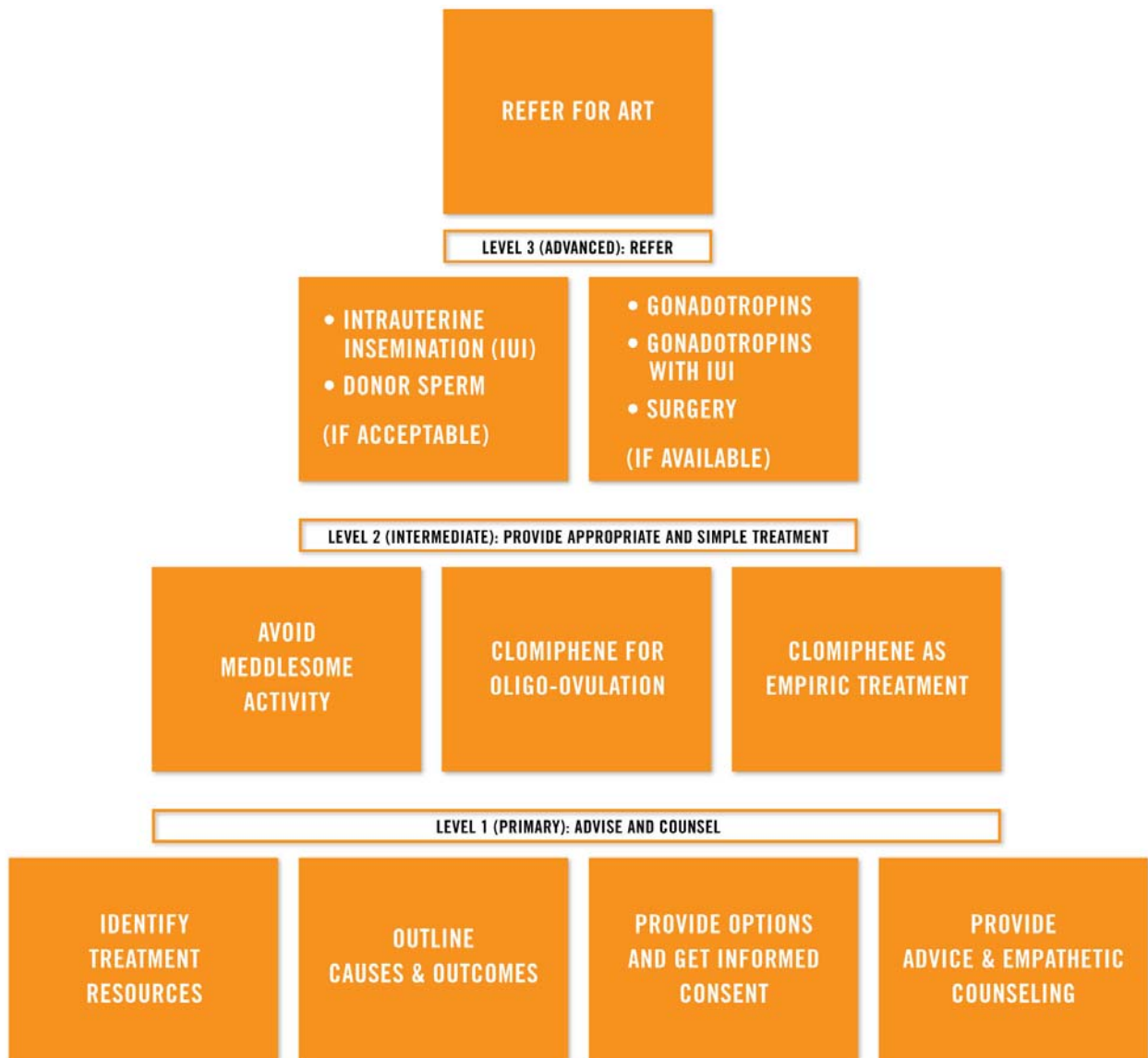
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Tools

Levels

Actions

THE FIGO FERTILITY TOOL 5: HOW TO TREAT INFERTILITY



BASIC TOOL 5: HOW TO TREAT INFERTILITY

Levels of Infertility Care and Services

The toolbox for treatment describes care at three levels from lowest resources/personnel/cost at the bottom of the pyramid to highest at the top.

Level 1 or Primary Care level services: Advise and counsel

The lowest level health care setting might be a simple primary health centre (PHC) run by a midwife and/or staff nurse as Primary Care Provider (PCP) or Health Provider (HP). The major activity at this level is to provide advice and counseling.

1. Identify treatment resources

Does the PCP or health provider (HP) have sufficient knowledge of fertility and infertility? Treatment choices are limited at Level 1, but fortunately access to treatment is not essential for infertile couples to conceive. Even so, infertile couples are not happy to wait for treatment. Thus the HP must determine what resources are available.

2. Outline causes and outcomes: The PCP should outline the cause of the infertility based on the history, physical examination and diagnostic tests. Available treatment resources should be identified and explained to the patient. The potential outcomes of treatment should be detailed and quantified to the extent possible.

3. Provide options and get informed consent: The PCP should list the appropriate and available options. The benefits/costs/risks and advantages/disadvantages of each option should be described and questions answered. The patient and provider should then choose the best option, and the Provider should obtain informed consent to proceed with treatment.

4. Provide advice and empathetic counseling: The PCP should provide comprehensive supportive counselling for infertility taking into account medical, cultural and socioeconomic issues. After obtaining informed consent the provider should continue to give advice and empathetic counselling regarding the chosen treatment.

Level 2 or Intermediate Care level services: Provide appropriate and simple treatment

Intermediate services represent a wide range of health care levels between Level 1 or Primary Care and the highest Level 3 or Advanced Care. At Level 2 there may be an opportunity to apply simple treatment when it is indicated.

1. Avoid meddling activity: These include strict coital timing, use of calendars and basal temperature recordings, none of which have been proven to increase the probability of pregnancy. Other meddling activities include unsubstantiated limitations or interventions on diet, medications, exercise or other activities that have not been shown to increase pregnancy rates and yet cause disruption, cost and stress in the patient's life.

2. Clomiphene citrate for oligo- anovulation: Clomiphene citrate is an effective treatment for oligo-ovulation and anovulation. It helps to cause regular ovulation and increases pregnancy

rates. It should be used only in properly selected patients and for the recommended amount of time. (See Support Tool 5 for Treatment)

- 3. Clomiphene citrate as empiric treatment:** When used empirically in ovulating women to stimulate the development of more than one follicle, clomiphene citrate increases pregnancy rates. It should be used only in properly selected patients and for the recommended amount of time. (See Support Tool 5 for Treatment)

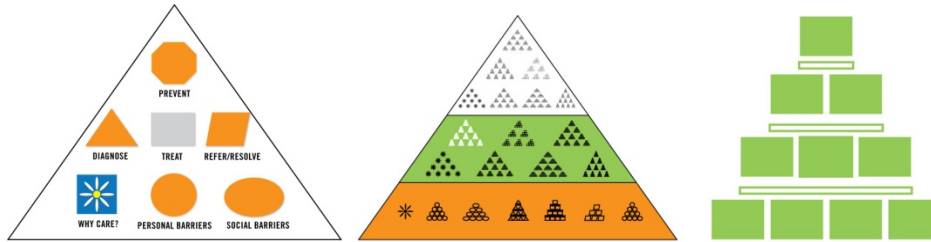
Level 3 or Advanced Care level services

Advanced services involve a tertiary hospital with diagnostic and therapeutic facilities similar to that found in referral hospitals in developed countries. The following treatments and actions can be undertaken with these resources if they are available, and if they are acceptable to the patient, their culture and their laws.

- 1. (a) Intrauterine Insemination (IUI):** IUI can be used with ovarian stimulation. IUI by itself may be helpful in cases in which there is male erectile dysfunction (ED) or other performance or male or female anatomic/physiologic problems that limit the ability to deposit sperm at the cervix at the appropriate time. IUI can also be helpful with cryopreserved/thawed sperm.
(b) Donor sperm: donor sperm can be used when available, appropriate and consistent with patient and society values and laws.
- 2. (a) Gonadotropin stimulation:** ovulation induction can be used for oligo-anovulation after clomiphene treatment failure and limited empiric Follicle Stimulating Hormone (FSH) treatment where IVF is not available.
(b) Gonadotropin stimulation with IUI: ovarian stimulation with IUI can be used for oligo-anovulation after clomiphene treatment failure and limited empiric FSH/IUI treatment where IVF is not available.
(c) Infertility surgery: tubal surgery, surgery for fibroids, adhesions and endometriosis is sometimes indicated. In highly selected patients laparoscopic ovarian drilling may be used for polycystic ovarian syndrome (PCOS). Hysteroscopic surgery may be indicated for polyps, myomas, intrauterine adhesions, cornual obstruction and uterine abnormalities such as septum. It is important to treat co-existing endocrine conditions and other female and male infertility diseases/disabilities.

Refer for ART Services

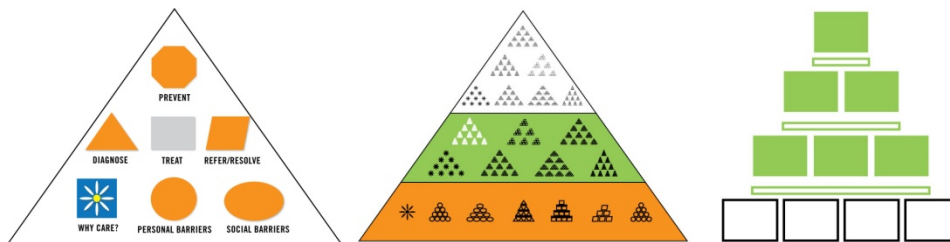
- 1. ART services:** if IVF is accessible it should be used as indicated. ICSI can be used selectively to treat male factor infertility. Preimplantation genetic diagnosis may be used in selected patients with genetically-based medical conditions. Adopt protocols to avoid ovarian hyperstimulation syndrome (OHSS) and multiple births. Blastocyst culture may have some applications. The use of donor sperm, donor oocytes, donor embryos and surrogates/gestational carriers in ART can be selectively used when available, appropriate and consistent with patient and society values and laws.



Support Tool 5: How to Treat Infertility

Levels of Infertility Care and Services

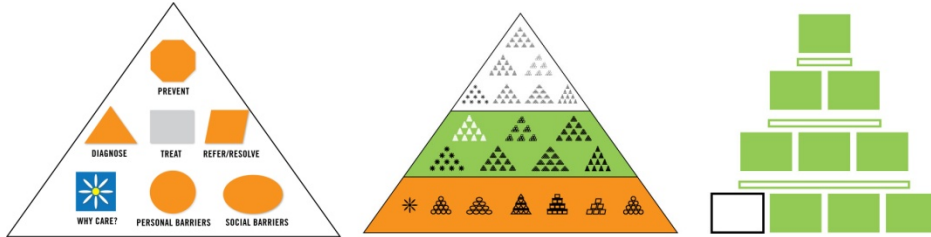
The toolbox for treatment describes care at three levels from lowest resources/personnel/cost at the bottom of the pyramid to highest at the top. The type of treatment that is provided to patients will depend on the resources that are available in that environment.



Level 1 or Primary Care level services: Advise and counsel

The lowest level health care setting might be a simple primary health centre (PHC) run by a midwife and/or staff nurse as Primary Care Provider (PCP) or Health Provider (HP). The major activity at this level is to provide advice and counseling.

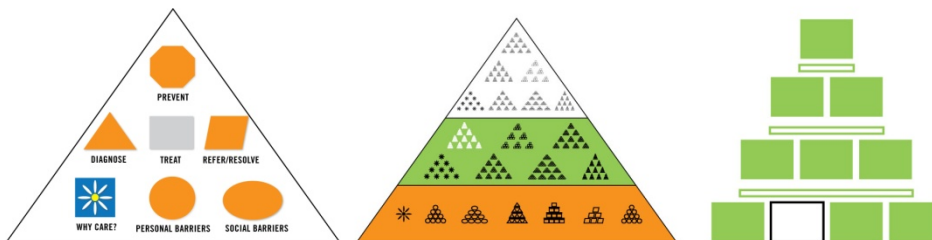
There are limited diagnostic or therapeutic possibilities. The PCP is primarily busy with obstetrical, pre- and perinatal care, family planning, and clinics for infants and small children. The PCP has to be encouraged to accept the health importance of childlessness and infertility. The following four headings describe the priorities for infertility treatment in Level 1 or Primary Care.



- 1. Identify treatment resources :** Does the PCP or health provider (HP) have sufficient knowledge of fertility and infertility? Treatment choices are limited at Level 1, but fortunately access to treatment is not essential for infertile couples to conceive. Even so, infertile couples are not happy to wait for treatment. Thus the HP must determine what resources are available.

Without treatment, pregnancy leading to live birth occurs within one year in more than 20% of couples (Hunault, 2004). Success is more likely if the woman is less than thirty years of age, if there has been a previous pregnancy in the partnership and if the couple has been trying for less than three years.

Even so, infertile couples are not happy to wait for treatment. Thus, the HP must ask what resources are available in this primary healthcare centre. Is clomiphene accessible? Are there laboratory facilities that would allow for sperm preparation for intrauterine insemination?



- 2. Outline causes and outcomes:** The PCP should outline the cause of the infertility based on the history, physical examination and diagnostic tests. Available treatment resources should be identified and explained to the patient. The potential outcomes of treatment should be detailed and quantified to the extent possible.

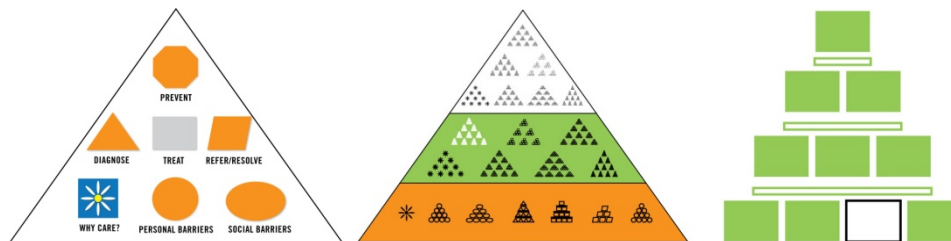
In order to advise on treatment, service providers should be familiar with common causes of infertility and their impact on the likelihood of pregnancy and birth within two or three years. In 20 follow-up studies involving over 14,000 infertile couples who had only non-ART treatments, the average likelihood of live birth was 31% (Collins and Van Steirteghem, 2004).

The three most common causes of infertility are problems with ovulation, sperm production or tubal disease (The Male Infertility Best Practice Policy Committee of the American Urological Association and Practice Committee of the American Society for Reproductive Medicine, 2006; ASRM, 2012c). It is less clear how endometriosis and peritubal adhesions might cause infertility. In a small fraction of couples, severe endometriosis and extensive tubal adhesions may distort the relationship between ovarian follicles and tubal fimbria, but the majority of cases with these diagnoses are not severe or extensive (Giudice and Kao, 2004). Although abnormal production of cervical mucus could cause infertility, the relevant diagnostic test is no longer recommended (ASRM, 2012c). Abnormalities of the uterus are uncommon causes of infertility, and their importance can be evaluated by means of a hysterosalpingogram when that test is available (ASRM, 2012c). In some couples more than one apparent cause of infertility may exist.

Even after a complete diagnostic assessment, however, reasons for the infertility may not be found. Thus, unexplained infertility may be a common diagnosis (Maheshwari, 2008). Where fewer tests are available to be done, it follows that there will be more couples with unexplained infertility.

Without treatment, the likelihood of pregnancy within two or three years is close to zero when there is complete lack of ovulation, absence of sperm or tubal obstruction. When ovulation does occur, but infrequently, or when there is tubal patency despite the presence of tubal disease, pregnancy rates are lower than in normal couples but still more than 20% within one year, which is far from zero (Hunault, 2004). Also, if sperm are present but the count is below normal, if the sperm have low motility or abnormal shape, average pregnancy rates are also lower than in normal couples but far from zero (Hunault, 2004).

With unexplained infertility, mild endometriosis and mild oligospermia live birth rates over two to three years are similar to the 31% average rates noted above (Collins and Van Steirteghem, 2004; ASRM, 2012c). In all types of infertility, age of the female partner, previous pregnancy and duration of infertility affect pregnancy rates.



- 3. Provide options and get informed consent:** The PCP should list the appropriate and available options. The benefits/costs/risks and advantages/disadvantages of each option should be described and questions answered. The patient and provider should then choose the best option, and the Provider should obtain informed consent to proceed with treatment.

For most infertility conditions there are alternative treatments, which should be explained. For whatever management is planned, the PCP should provide sufficient information about benefits, risks and costs to allow the couple to give informed consent. (The FIGO Committee for the Study of Ethical Aspects of Human Reproduction and Women's Health, 2009)

After the available diagnostic evaluation has been completed, the couple's choices are to wait without treatment, to utilize whatever simple treatment is available locally, or to ask for referral to a higher level for treatment. Simple treatment that may be available locally is discussed under the Level 2 heading. Referral pertains to treatments available under the Level 3 heading.

In a summary of three follow-up studies of infertile couples who did not receive treatment, the average likelihood of pregnancy within one year, leading to a live birth, was 20% or more (Hunault, 2004). For an individual couple, the prognosis without treatment can be estimated from a complex prediction model generated in that study. More simply, a couple's expected prognosis also can be approximated from numbers based on the same model. The 20% average pregnancy rate is increased by about 1% for each year of female age under 30 years, increased by about 5% if the duration of infertility is less than three years, and increased by about 8% if the couple have secondary infertility. Thus waiting for one more year without treatment is not a hopeless choice.

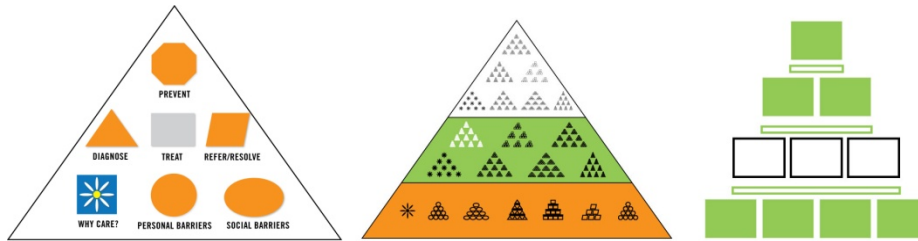


4. Provide advice and empathetic counseling: The PCP should provide comprehensive supportive counselling for infertility taking into account medical, cultural and socioeconomic issues. After obtaining informed consent the provider should continue to give advice and empathetic counselling regarding the chosen treatment.

Advice includes information about infertility outcomes. There are five outcomes for couples who receive clinical care for infertility:

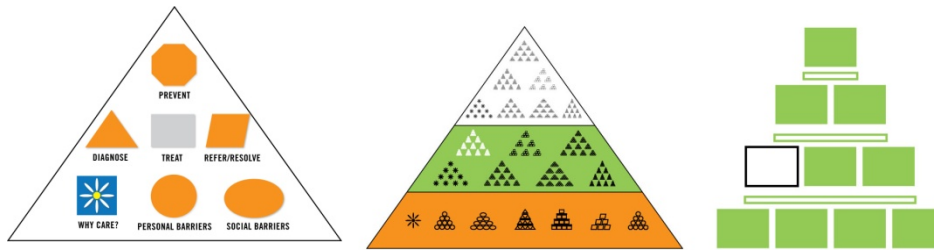
1. success, in the form of a live birth;
2. partial success - a miscarriage or ectopic pregnancy confirms the ability to conceive;
3. adoption, which is a rarity in many parts of the world;
4. failure without resolving the distress, and
5. resolution or coming to terms with the inability to have children.

The majority of infertile couples do not conceive, even when assisted reproductive treatment is available. Thus, it is helpful to ensure that the clinical process is not harmful or unpleasant. This means that even when interventions are not available, the HP should acknowledge that infertility is a disease, provide prompt attention when they visit, encourage discussion, and provide information in a caring and sympathetic environment (Ryan, 1999). While empathetic counselling may not improve pregnancy rates, the very least that infertile couples should be given is sympathetic, informed and humane health care.



Level 2 or Intermediate Care level services: Provide appropriate and simple treatment

Intermediate services represent a wide range of health care levels between Level 1 or Primary Care and the highest Level 3 or Advanced Care. At Level 2 there may be an opportunity to apply simple treatment when it is indicated.



- 1. Avoid meddlesome activity:** These include strict coital timing, use of calendars and basal temperature recordings, none of which have been proven to increase the probability of pregnancy. Other meddlesome activities include limitations or interventions on diet, medications, exercise or other activities that have not been shown to increase pregnancy rates and yet cause disruption, cost and stress in the patient's life.

Conscientious clinicians naturally try to help patients, and when medical therapy is not available they may resort to suggestions about rest, life style, diet and other diversions. With respect to infertility, there is a fertile window in the six days ending on the day of ovulation (ASRM, 2008a). Thus, infertility clinicians commonly recommend timing of intercourse according to the menstrual calendar or another indicator of the occurrence of ovulation, such as cervical mucus or a urinary LH test. This advice is not supported by good quality evidence.

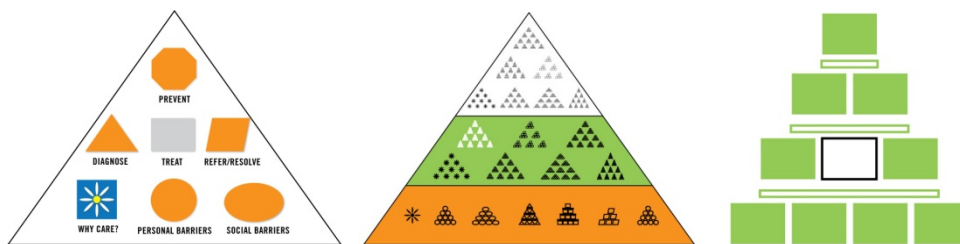
When cohabiting couples are having coitus two to three times weekly, there is no evidence from natural cycles among infertile couples that strict coital timing, more frequent intercourse, use of calendars or basal temperature recordings increase the likelihood of conception. In fact, there is good quality evidence that timing methods may not work from studies in cycles of clomiphene citrate administration or intrauterine insemination: pregnancy rates were similar with all of the methods of timing (Johnson, 2011; Smith, 1998). Also, no good quality evidence supports the suggestion to decrease frequency of

intercourse in the non-fertile period. Of course, if the couple seldom has intercourse, it would be helpful to suggest increasing the frequency during the fertile period

If information on timing intercourse has no known effect on pregnancy rate, does this advice have other benefits? Advice on how to recognize the fertile period may help to involve the couple in their management; also, it may allow them to sense that they are taking some action. At the same time, a forced change in their natural pattern of intercourse may cause tension and have adverse effects in the life of the couple. Judgment is needed in each case, but in the infertility setting supportive counselling may be preferable to unproven suggestions and interventions. Clearly, it is also important to avoid meddlesome procedures such as endometrial biopsy or dilatation and curettage.

Interim summary

- Advice about diet, life style and rest is usually not based on evidence.
- Advice about intercourse timing usually is not helpful or based on evidence.
- Avoid unnecessary procedures.



- 2. Clomiphene citrate for oligo-anovulation:** Clomiphene citrate is an effective treatment for oligo-ovulation and anovulation. It helps to cause regular ovulation and increases pregnancy rates. It should be used only in properly selected patients and for the recommended amount of time.

Lack of ovulation or infrequent ovulation may be revealed by an abnormal menstrual history. This would be the only cause of infertility which may be evident without formal testing. Whether it should be treated without proving that sperm are available and the tubes are patent depends on the circumstances. If these tests are not available, a trial of ovulation induction may be indicated.

While pregnancy occurs occasionally among untreated women with oligo-anovulation, induction of ovulation is the usual treatment when they seek medical care. This can be achieved primarily with clomiphene citrate or metformin (Brown, 2009; Johnson, 2011; ASRM, 2006b). Although letrozole is associated with equivalent pregnancy rates (He and Jiang, 2011), it is not approved in most countries for this purpose.

Clomiphene citrate is taken orally, usually starting on the third to fifth day after the onset of spontaneous or induced menses. The usual dose of clomiphene citrate is 50 mg per day for 5 days. The dose may be increased by 50 mg increments in subsequent cycles until ovulation is induced. Most women ovulate after 50 mg daily (52%) or 100 mg daily (additional 22%); it is unwise to use a higher dosage than 150 mg daily. If there is no ovulatory response after 6 cycles, success is unlikely. The live birth rate within 12 months was 42% for all treated women and 56% among those who ovulated (Imani, 2002; ASRM, 2006b).

Clomiphene citrate treatment is an effective treatment. In addition to the uncontrolled studies cited in the previous paragraph, three randomized controlled trials involving 70 clomiphene-treated patients and 63 control women were summarized in a Cochrane review (Brown., 2009). Pregnancy is over four times more likely in clomiphene-treated patients (rate ratio 4.5, 95% CI 1.4, 14.5) compared with untreated controls. During the three or four months of the studies, there were only two pregnancies in the 63 untreated women (about 3%). The pregnancy rate was 17% (95% Confidence Interval 6, 28) higher in treated women, which means that treated women had 17% more pregnancies than controls during the average three to four month trial. This also means that there would be one additional pregnancy for every six patients treated with clomiphene compared with controls during treatment.

Although clomiphene citrate treatment is usually free from immediate adverse effects, a minority of women experience hot flushes (10%) or changes in affect, which may cause some women not to want further treatment. Temporary visual disturbances such as blurring or double vision occur in about 2% of women. Clomiphene citrate treatment should be discontinued when this occurs. (ASRM, 2006b).

The most serious complication of clomiphene citrate treatment is multiple births, which occurs in about 8% of pregnancies arising in clomiphene-treated cycles. While the vast majority are twins, triplet, quadruplet and quintuplet pregnancies may occur less than 1% of the time. Mild ovarian hyperstimulation syndrome (OHSS) with ovarian enlargement and moderate pain is uncommon and severe OHSS with major ovarian enlargement, severe abdominal pain and ascites is extremely rare. Clomiphene treatment does not increase risks of miscarriage or congenital anomalies. The first reports on ovarian cancer risk caused concern, but that has been nullified by more recent reports. (ASRM, 2006b)

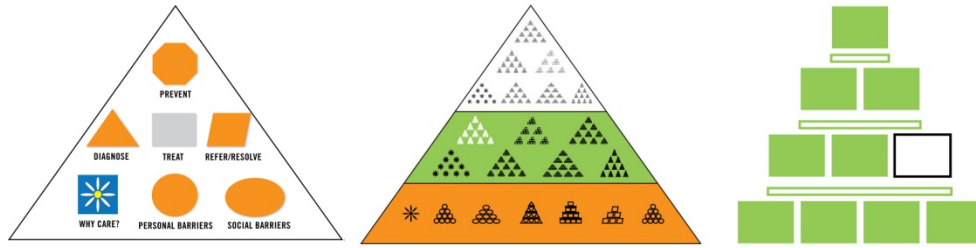
Clinicians monitor clomiphene citrate treatment cycles to determine whether ovulation has occurred and to rule out side effects and adverse events such as OHSS. Pregnancy rates and complication rates are unaffected, however, by whether cycles are monitored with basal temperature records, urinary LH, or pelvic ultrasound. Under ideal circumstances monitoring would include monthly clinical assessments to check menstrual records and document symptoms, as well as regular assessment of serum progesterone and/or use of serial ultrasound to observe follicular changes. Because cycles may not be regular, the likelihood of serum progesterone being mid-luteal can be increased by arranging weekly tests starting two weeks after the last clomiphene pill and continuing until the next menses (ASRM, 2006b). If serum progesterone estimations are not available, however, clomiphene citrate treatment cycles can be monitored by clinical assessment only.

Metformin has been used for ovulation induction, usually for non-obese women with oligo-anovulation due to polycystic ovary syndrome. In a meta-analysis of three trials involving 285 women, live birth rates were similar in the groups on metformin and clomiphene citrate (30.3% and 30.8%, respectively) (Johnson, 2011). Metformin dosage is 1,000 to 2,000 mg/day (divided in 2 to 4 doses). Metformin is more expensive and there is a high frequency of severe gastrointestinal side effects such as nausea, vomiting, or diarrhoea. Metformin is not, however, associated with multiple pregnancies. In most settings, metformin is reserved for women who prove resistant to clomiphene citrate. With metformin and clomiphene citrate together there are combined costs and complications which are not worth the small added benefit (ASRM, 2006b).

Again, meddlesome activities with other medications or treatments should be avoided unless a diagnosis has been established and there is a reasonable chance of treatment being effective.

Interim summary

- Clomiphene citrate is an effective treatment for oligo-anovulation.
- Monitoring by means of serum progesterone estimation is helpful.
- Metformin is an alternative in women who can tolerate the side effects.



3. Clomiphene citrate as empiric treatment: Clomiphene citrate is an effective treatment when used empirically in ovulating women to stimulate the development of more than one follicle, which increases pregnancy rates. It should be used only in properly selected patients and for the recommended amount of time.

Clomiphene citrate is widely used with or without intrauterine insemination (IUI) as an empiric treatment in the hope that it will increase the number of follicles and bring sperm into closer approximation with the oocyte(s). Empiric treatment is used when the cause of the disease is unknown or the treatment used is not specific to the supposed cause of the disease. Simple empiric treatment involves the couple in their management and can serve as a cheaper alternative to more costly empiric treatment such as in vitro fertilization (IVF).

As with many other empiric therapies, however, this use is not consistently supported by unbiased evidence and the treatment is not free from harm. Although empiric therapy has been evaluated mainly among couples with unexplained infertility, the principles also apply to couples with a supposed reason for their infertility if they have not responded to conventional therapy.

Among several trials that compared clomiphene treatment with placebo among couples with unexplained infertility, only two are sufficiently free from bias (Bhattacharya, 2008; Fisch, 1989) to provide information on effectiveness. The larger trial involved a 50 mg dosage for five days per cycle among 385 couples with 2.5 years median duration of infertility. The pregnancy rates were 14% in the treated couples and 17% in the untreated couples. This trial was sufficiently well-powered to rule out a likely benefit from using clomiphene citrate as an empiric treatment. The other trial, however, opens a window on a potential benefit in couples with longer duration of infertility. This trial involved a 100 mg dosage for five days per cycle among 148 couples with 4.3 years mean duration of infertility. The pregnancy rates were 13% in the treated couples and 6% in the untreated couples, a difference which was not significant. It is interesting that the pregnancy rate with 100 mg CC (13%) was not higher than with the 50 mg dose (14%).

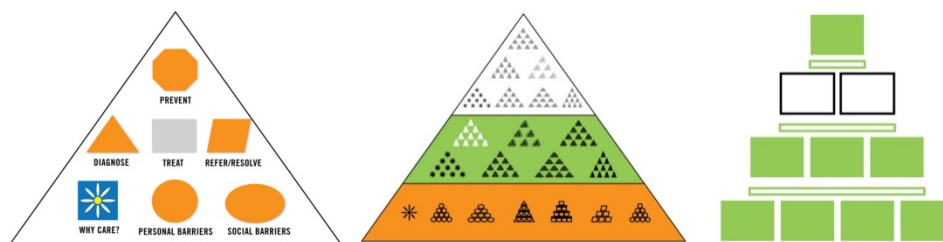
Table 1. Two RCTs on clomiphene citrate for unexplained infertility.

Authors	Fisch et al., 1989	Bhattacharya et al., 2008
Control treatment	placebo	expectant
CC dosage per day for 5 days	100 mgs	50 mgs
Female age (yrs)	30	32
Duration of infertility (yrs)	4.3	2.5
Clomiphene citrate pregnancies		
Number	10	26
Couples (% per couple)	76 (13)	192 (14)
Cycles (% per cycle)	290 (3)	883 (3)
Control pregnancies		
Number	4	32
Couples (% per couple)	72 (6)	193 (17)
Cycles (% per cycle)	274 (1)	n/a

While both trials achieved similar pregnancy rates with CC treatment, the pregnancy rates in the controls were different: 17% in those with average 2.5 years duration of infertility and 6% in those with 4.3 years. The 100 mg trial lacked power to rule out a null effect in couples with a longer duration of infertility. Thus, clomiphene citrate is not a useful empiric treatment, although the studies lack the power needed for a definitive answer among couples with duration of infertility more than four years. Any response to empiric therapy is likely to occur with 3-6 cycles of treatment.

Interim summary

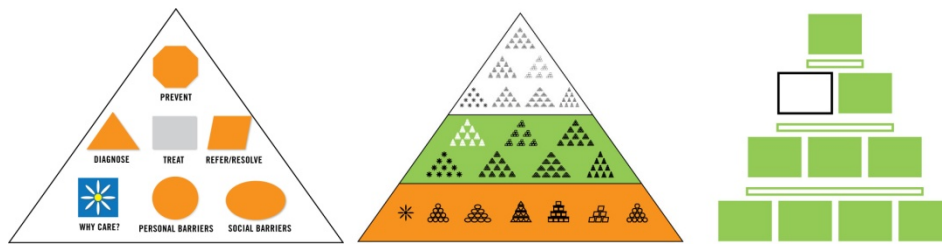
- The evidence shows that clomiphene citrate is not an effective empiric treatment for couples with less than three years duration of infertility.
- The evidence is inconclusive about clomiphene citrate as an empiric treatment for couples with three or more years duration of infertility.



Level 3 or Advanced Care level services

Advanced services involve a tertiary hospital with diagnostic and therapeutic facilities similar to that found in referral hospitals in developed countries. The following treatments and actions can be undertaken with these resources if they are available, and if they are acceptable to the patient, their culture and their laws.

Advanced services involve a tertiary hospital with diagnostic and therapeutic facilities as in referral hospitals in developed countries, but lacking in ART services. The relevant services for infertile couples include intrauterine insemination (IUI), use of donor sperm if available and acceptable to the patient and society, gonadotropin treatment and infertility surgery.



- 1. (a) Intrauterine Insemination (IUI):** IUI can be used with ovarian stimulation. IUI by itself may be helpful in cases in which there is male erectile dysfunction (ED) or other performance or male or female anatomic/physiologic problems that limit the ability to deposit sperm at the cervix at the appropriate time. IUI can also be helpful with cryopreserved/thawed sperm.

Many clinicians combine clomiphene citrate with intrauterine insemination (IUI). By itself, IUI has little value. Three parallel design trials have evaluated IUI alone as an empiric treatment for unexplained infertility (Bhattacharya, 2008; Guzick, 1999; Steures, 2007). In two trials involving 467 and 99 couples, the pregnancy rate in IUI cycles was 2.2% (95% CI 0.4, 4.1) higher than in control cycles (Guzick, 1999; Steures, 2007). In the other trial, which involved 384 couples, the pregnancy rates were 22% and 19% in treated and control groups, respectively (Bhattacharya, 2008). In the one trial with a difference in favour of IUI, the difference in pregnancy rates per cycle was small: 5% and 3% with IUI and intracervical insemination, respectively and the duration of infertility was 3.7 years (Guzick, 1999). Intrauterine insemination alone as an empiric treatment should be reserved for couples with more than three years duration of infertility who are willing to accept a small increment in pregnancy rates. It may also be useful in some couples with sexual dysfunction. IUI with carefully prepared sperm is not associated with notable side effects.

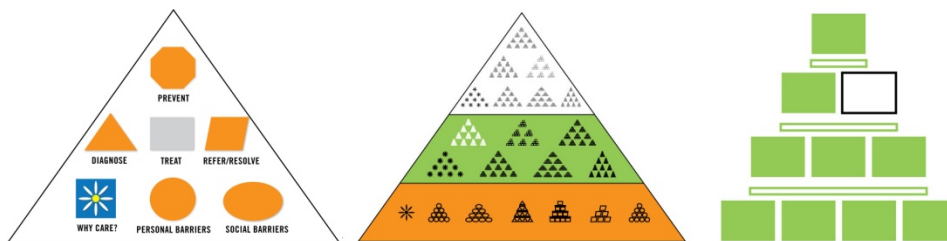
The combination of clomiphene citrate with IUI (CC/IUI) is commonly used as an empiric treatment, although there is limited evidence of its effectiveness. One crossover trial reported on 176 treatment cycles before the crossover. In the CC/IUI group the pregnancy rate was 11% per cycle compared with 4% in the control group (95% CI -1.0,15.2) (Deaton, 1990). The results of a large management trial support this apparent benefit. Both arms received CC/IUI as an initial treatment, and the pregnancy rates were 7% and 8% per cycle and 19% and 22% after three cycles (Reindollar, 2010). Where facilities permit the use of CC/IUI treatment, a course of three cycles is a reasonable trial of empiric therapy.

Interim summary

- Fair evidence indicates clomiphene citrate treatment with intrauterine insemination achieves a pregnancy rate of about 7% per cycle.

1. **(b) Donor sperm:** donor sperm can be used when available, appropriate and consistent with patient and society values and laws.

Where ethically acceptable in cases of infertility due to azoospermia, timed intrauterine insemination of carefully selected and prepared donor semen is the most effective of all infertility treatments. The identification and screening of donors involve procedures that are laborious, although not technically demanding. Cryopreservation is necessary while awaiting the results of later testing for sexually transmitted infections. When three to six intrauterine insemination cycles are not successful, ICSI with donor sperm may be considered.



2. **(a) Gonadotropin stimulation:** ovulation induction can be used for oligo-anovulation after clomiphene treatment failure and limited empiric Follicle Stimulating Hormone (FSH) treatment where IVF is not available.

Gonadotropin treatment can be used for ovulation induction in women with infertility due to a severe ovulatory disorder, or as empiric treatment in those who have no alternative but IVF. Gonadotropin treatment should only be used where there are ultrasound facilities to identify the number of maturing follicles in order to improve effectiveness and avoid excessive ovarian stimulation.

b)

Gonadotropin ovulation induction:

Amenorrhea or oligomenorrhea reflect anovulation or oligoovulation, respectively. Elevated FSH values imply ovarian failure or World Health Organization (WHO) Type III Ovulatory Disorder which cannot be treated with gonadotropins. If the FSH values are low to normal, however, gonadotropin treatment may be indicated. Anovulation may be due to hypothalamic amenorrhea, (WHO Type I) in which case FSH levels are low to low-normal, but the most common underlying disorder is polycystic ovarian syndrome (PCOS), which is included in the WHO Type II group and is usually treated initially with clomiphene citrate. (ASRM, 2008)

The indications to use gonadotropins for ovulation induction in the WHO Type II group with oligo-anovulation are (1) when clomiphene citrate treatment has failed to stimulate ovulation after 3 cycles and (2) when ovulation occurs with clomiphene citrate treatment, but there is no pregnancy after 3 to 6 cycles.

In clinical protocols in women without menses, gonadotropin treatment is usually started after a progestin-induced menses, at a fairly low dosage of 37.5 to 75 International Units (IU) per day,

using the cheapest approved preparation of gonadotropin available. When ultrasound monitoring shows one or two mature follicles at around 16-18 mm diameter, release of the oocyte can be induced with human chorionic gonadotropin (hCG), recombinant luteinizing hormone (LH) or gonadotropin releasing hormone (GnRH) agonist. With more than two mature follicles, the risk of multiple pregnancy is excessive. Ovulation will usually occur 24 to 48 hours after the hCG injection, and timely intercourse should be arranged (ASRM, 2008b; ASRM, 2008c).

There are no trials of the effectiveness of gonadotropin treatment for ovulation induction because, with untreated pregnancy rates around 2% (Brown, 2009), treatment-associated pregnancy rates above 10% are unlikely to be due to bias. In 13 studies involving 1,269 cycles and 881 anovulatory infertile women who received gonadotropin treatment, the pregnancy rate was 15% per cycle and 41% per patient (Mulders, 2003). Pregnancy rates are higher in women with hypothalamic amenorrhea (25% per cycle) than in those with PCOS (8% per cycle) (Fluker, 1994).

Multiple pregnancy and ovarian hyperstimulation syndrome (OHSS) are the most frequent adverse events after ovulation induction treatment. Prevention of multiple births depends on cancelling the cycle if there are more than two mature follicles; OHSS frequency and severity can be minimized by using lower dosages of hCG or replacing hCG with recombinant LH or GnRH agonist. (ASRM, 2008i; ASRM, 2012b)

Interim summary

- In women with infertility due to oligo-anovulation where treatment with clomiphene citrate or metformin is unsuccessful, fair evidence shows that gonadotropin treatment is effective.
- Fair evidence shows that the pregnancy rate is higher with hypothalamic amenorrhea than it is with polycystic ovarian syndrome.
- Protocols should attempt to minimize risk of multiple pregnancy and ovarian hyperstimulation syndrome.

2.(b) Gonadotropin ovarian stimulation with IUI: ovarian stimulation with IUI can be used for oligo-anovulation after clomiphene treatment failure and limited empiric FSH/IUI treatment where IVF is not available.

When IVF is not accessible, gonadotropin ovarian stimulation followed by IUI is used as empiric therapy. This application is usually in couples with unexplained infertility after they have tried milder treatments without success, or with other diagnoses after standard treatment has been tried without success. Since the aim is to increase the number of mature follicles, the added likelihood of pregnancy comes with an added risk of multiple pregnancy.

Two trials provide seemingly contradictory evidence about the effectiveness of gonadotropin ovarian stimulation with IUI. The treatment was effective in couples with prolonged infertility (Guzick, 1999) but not in couples who have a good prognosis and a duration of infertility which is less than three years (Steures, 2006). While there were differences in the control treatment and the gonadotrophin dosages, the difference in duration of infertility is sufficient to explain the apparent contradiction (Table 2).

Table 2. Two RCTs on gonadotropin and IUI treatment

Authors	Guzick, 1999	Steures, 2006
Mean duration of infertility (yrs)	3.5	2.0
Mean female age (yrs)	32	33
Treatment pregnancies		
Couples number/total (%)	77/231 (33)	29/127 (23)
Cycles number/total (%)	54/618 (9)	29/676 (4)
Control pregnancies		
Number	23	34
Couples (% per couple)	23/233 (10)	126 (27)
Cycles (% per cycle)	14/706 (3)	737 (5)

The Guzick trial (1999), involved 4 cycles of gonadotropin IUI in the treatment group and four cycles of intracervical insemination (ICI) in the control group. The Steures trial (2006) involved 6 cycles of gonadotropin IUI or six months of expectant treatment. The objective of gonadotropin treatment was different in the trials: in the Guzick (1999) trial, 150 IU of follicle-stimulating hormone daily until at least two follicles reached 18 mm; in the Steures trial (2006), 75 IU daily until at least one follicle reached 16 mm.

The gonadotropin regimen in the Steures trial (2006) achieved a 23 % pregnancy rate per couple, compared with 33% with the more aggressive regimen used in the Guzick trial (1999). The aggressive gonadotropin regimen, however, yielded three sets of quadruplets, four sets of triplets and 18 twin births in the 80 pregnancies during gonadotropin/ICI or IUI cycles, a 32% multiple birth rate. There were only four multiple births (two triplet and two twin births) in the Steures trial (2006). The calculated singleton pregnancy rates for the trials are 23% and 20% for aggressive and non-aggressive gonadotropin regimens, respectively.

The main difference between the trials, however, is the pregnancy rate in the control groups: 10% in the Guzick trial (1999) versus 27% in the Steures trial (2006). This is associated with longer duration of infertility (3.5 versus 2.0 years) in the former trial. In a hypothetical scenario, the pregnancy rate with the Guzick regimen would not be significantly better than that in the Steures controls and the pregnancy rate with the Steures regimen would be significantly better than that in the Guzick controls.

In practice, it is critical to consider the clinical setting: the couple, the protocol and the monitoring facilities. With respect to the clinical setting, given that the risks of multiple pregnancy are exaggerated in limited resource settings, non-aggressive regimens are essential. With respect to the couple, unless the duration of infertility is more than three years, expectant management is as effective as gonadotropin/IUI treatment. With respect to the facilities, careful monitoring with ultrasound is needed to minimize multiple birth. It is important to inform

couples, however, that the pregnancy rates per cycle of moderate gonadotropin/IUI treatment are in the same range as those from CC/IUI treatment.

A key management trial (FASST) involved 503 couples with unexplained infertility that were randomly allocated to three cycles of CC/IUI and then up to six cycles of IVF or to three cycles of CC/IUI, then three cycles of gonadotropin/IUI before the IVF cycles. The group who did not have gonadotropin/IUI achieved more pregnancies sooner at lower cost than the group that was randomized to all three steps (Reindollar, 2010). Thus, where IVF is available, gonadotropin/IUI treatment has no added value.

Interim summary

- Good evidence shows that gonadotropin-intrauterine insemination is not an effective empiric treatment if the duration of infertility is less than three years. .
- Good evidence shows that while gonadotropin-intrauterine insemination is an effective empiric treatment in couples with three or more years duration of infertility, the benefit is small.
- Gonadotropin-intrauterine insemination treatment can be associated with an unacceptable likelihood of multiple pregnancy. Protocols should be used which minimize this risk.
- Good evidence shows that where in vitro fertilization treatment is available, there is no added value from having gonadotropin-intrauterine insemination treatment first.

2.(c) Infertility surgery: tubal surgery, surgery for fibroids, adhesions and endometriosis is sometimes indicated. In highly selected patients laparoscopic ovarian drilling may be used for polycystic ovarian syndrome (PCOS). Hysteroscopic surgery may be indicated for polyps, myomas, intrauterine adhesions, cornual obstruction and uterine abnormalities such as septum. It is important to treat co-existing endocrine conditions and other female and male infertility diseases/disabilities.

The value of infertility surgery depends on good diagnostic facilities for tubal disease, adhesions, endometriosis, fibroids and other anatomical abnormalities, on modern surgical facilities and on the availability of personnel trained in their use. (ASRM, 2008a; ASRM, 2008f; ASRM, 2012a; ASRM and SRS, 2012a; ASRM and SRS, 2012b)

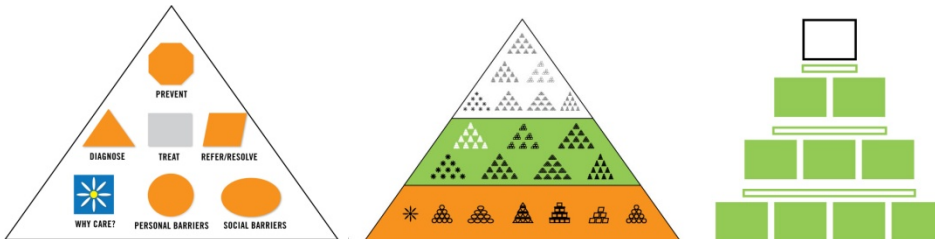
Surgery may be indicated for tubal obstruction, pelvic adhesions or severe endometriosis when the pathology clearly prevents access of spermatozoa to the oocyte or creates a barrier to the transport of the embryo. There are no randomized controlled trials, but these are not necessary when the likelihood of pregnancy without treatment is near zero, as it is in the most severe stages of tubal disease and endometriosis. Surgery, however, does not restore normal pregnancy rates.

The basic requirements for a good infertility surgery service are: adequate instrumentation and sterilizing procedures, experienced surgeons, a good anaesthesia service, continuous monitoring facilities and good post-operative care.

With tubal obstruction, if IVF is available, it is a matter of judgment whether to recommend surgical repair of the Fallopian tubes (with the potential for future fertility) or IVF with the potential need for repeated costly cycles. While the cost of tubal surgery is similar to that of one

or two IVF cycles, if tubal surgery is effective, it may be possible to have more than one pregnancy.

Treat co-existing endocrine conditions. During the assessment for infertility, co-existing endocrine or other medical conditions may become apparent, which should be treated. These include premature menopause, obesity, anorexia, diabetes and thyroid disease.



Refer for ART Services

- 1. ART Services:** If IVF is accessible it should be used as indicated. ICSI can be used selectively to treat male factor infertility. Preimplantation genetic diagnosis may be used in selected patients with genetically-based medical conditions. Adopt protocols to avoid ovarian hyperstimulation syndrome (OHSS) and multiple births. The use of donor sperm, donor oocytes, donor embryos and surrogates/gestational carriers in ART can be selectively used when available, appropriate and consistent with patient and society values and laws.

In vitro fertilization (IVF)

In vitro fertilization (IVF) is indicated in tubal disease, and with intra-cytoplasmic sperm injection (ICSI), in cases of severe male infertility. The majority of cycles worldwide, however, involve use of IVF or ICSI as an empiric treatment for a wide range of diagnoses after other treatment has failed. The live birth rates per cycle in most diagnostic groups are similar to those in couples with tubal disease or male infertility. (ASRM and SART, 2012a; ASRM and SART, 2012b; ASRM and SART, 2012c)

Live birth rates average 25% to 30% per IVF cycle started. In couples with tubal obstruction or severe male infertility, this is a dramatic improvement over the expected rates without treatment and RCTs are not necessary to demonstrate effectiveness. In other diagnoses, however, even after three years duration of infertility there remains a small but real chance of pregnancy without treatment. In a trial of immediate IVF versus a 90 day delay before IVF in 139 infertile couples with Fallopian tube patency, the likelihood of delivery was 21-fold higher in the treated group (95% CI 2.8, 155) (Hughes, 2004). The delivery rates were 29% and 1% in the IVF and delay groups, respectively. For every four women, there was one more birth in the IVF group than in the delayed group. In the FASTT management trial, the pregnancy rates averaged 31% in the two IVF groups (Reindollar, 2010).

The methods for IVF and ICSI involve ovarian stimulation, usually while pituitary activity is disabled to prevent premature ovulation, induction of ovulation, ultrasound-guided transvaginal oocyte retrieval, fertilization by surrounding oocytes with prepared sperm (IVF) or by injecting a single sperm into the oocyte cytoplasm (ICSI). The best embryos are transferred to the

endometrial cavity on the second to fifth day after retrieval, and progesterone or hCG are given to support the luteal phase. (ASRM and SREI, 2008)

Adopt protocols to avoid OHSS and multiple births.

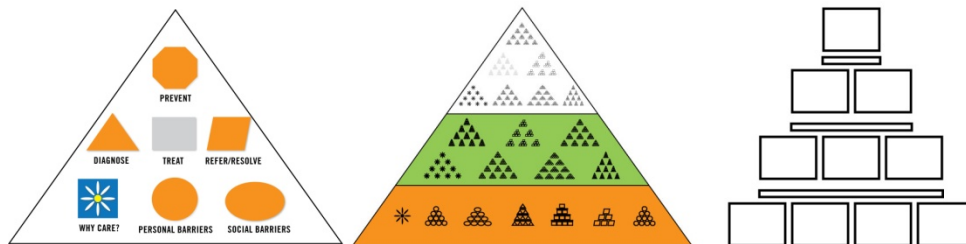
The risks of ovarian stimulation include multiple pregnancy and ovarian hyperstimulation syndrome (OHSS). (ASRM 2012b; ASRM, 2008i) Multiple pregnancy, with the attendant risks of preterm birth, should be avoided in all clinical settings, but especially in low resource settings. Although ovarian stimulation in IVF cycles could be done with lower dosages of drugs and less monitoring than is standard in developed countries, a protocol that will achieve good pregnancy rates without multiple birth rates has not yet been found.

Of course, multiple pregnancy rates would not be increased above normal if only one embryo was transferred in an IVF or ICSI cycle. The number of embryos transferred in the IVF trials cited above was 2.0 (Hughes, 2004) and 2.3 (Reindollar, 2010). Single embryo transfer generally results in lower pregnancy rates unless the couples come from the group with a good prognosis (Min, 2010). Good prognosis usually involves female age less than 37 years and a sufficient ovarian response, fertilization and embryo development that at least two high quality embryos are available for transfer. None of the relevant single embryo trials pertain to low resource countries. Nevertheless, it would be prudent in all low resource settings to adopt mild ovarian stimulation protocols and elective single embryo transfer policies in good prognosis patients.

Refer when possible.

When an advanced centre does not provide the services required by a couple, such as IVF, donor insemination, oocyte insemination or tubal surgery, it should be prepared to refer the patient where possible to a centre where the necessary service is available.

Other specialized services such as the use of donor oocytes, donor embryos, surrogates/gestational carriers and unconventional parenting create novel and challenging clinical situations for the infertility specialist. Referral to other centres, including those across borders and jurisdictional boundaries, are extremely complex and often unique. Providers and their teams have to determine for themselves how they can best meet their professional obligations to their patients while remaining faithful to their own values as well as the values and laws of their society. (ASRM and SART, 2008a)



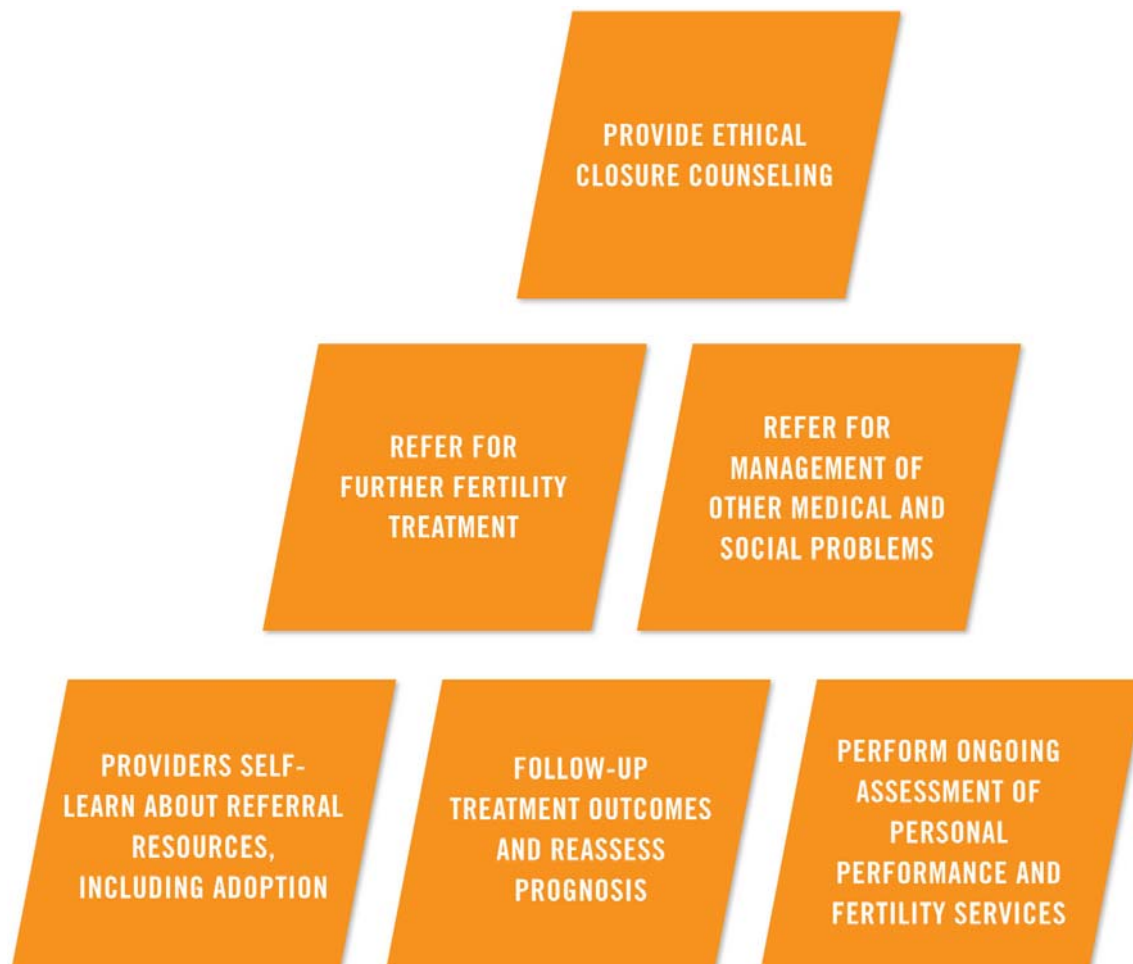
**REFERENCE TOOL 5:
HOW TO TREAT INFERTILITY**

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THE FIGO FERTILITY TOOL 6: HOW TO REFER AND/OR RESOLVE INFERTILITY



BASIC TOOL 6: HOW TO REFER AND/OR RESOLVE INFERTILITY

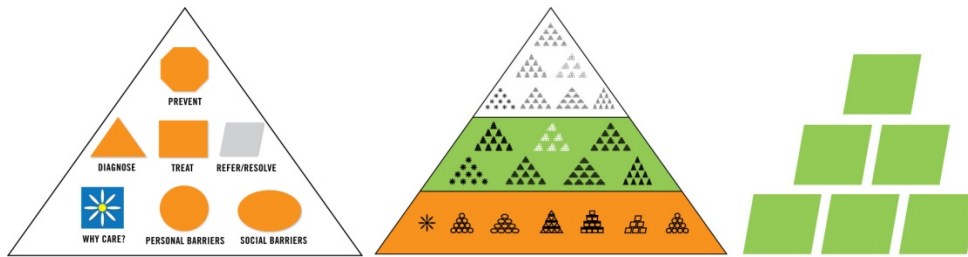
- 1. Providers self-learn about referral resources, including adoption:** To facilitate referral, healthcare providers should educate themselves to be aware of the relevant components and resources of the healthcare system that can be used to prevent and manage infertility.
- 2. Follow up treatment outcomes and reassess prognosis:** Determine appropriate follow-up intervals according to age, duration of infertility, patient clinical factors, patient socioeconomic / cultural factors and available infertility services.

3. **Perform ongoing assessment of self and fertility services:** To continually improve the services provided, infertility healthcare providers should
 - a. Set up an on-going self-assessment for the services they are providing.
 - b. Evaluate their personal performance on a routine basis.
 - c. Assess the accessibility and quality of their services on a routine basis.
 - d. Continue to educate themselves so that they can provide improved services to as many patients as possible who will benefit from their care.

4. **Refer for further fertility treatment:** Refer for further more specialized or sophisticated fertility treatment in the nearest / most accessible facility for the patient.

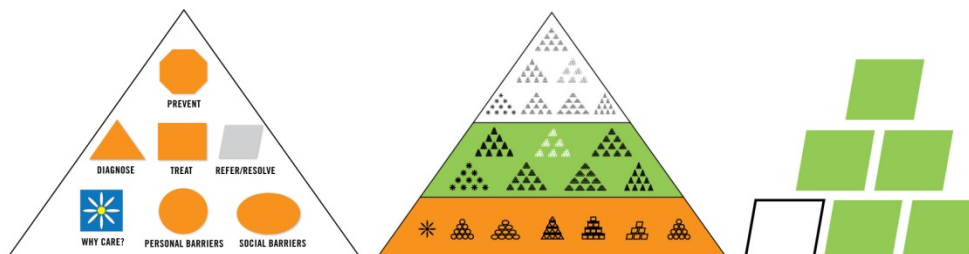
5. **Refer for management of other medical and social problems:**
 - a. Determine whether social services and marital counselling services are available and refer when indicated.
 - b. Refer for management of any co-existing medical conditions.

6. **Provide ethical closure counseling:** Understand the cultural aspects of infertility and its ethical considerations .To facilitate closure healthcare providers should
 - a. Recognize when closure counselling is needed.
 - b. Educate themselves to be aware of and evaluate available adoption services.



SUPPORT TOOL 6: HOW TO REFER AND/OR RESOLVE INFERTILITY

Except in optimal situations, only approximately half of all infertility patients will have a child as a result of treatment. In most low resource settings the likelihood of an infertile patient taking home a baby is almost certainly less than this. Therefore, it is important for health care providers to know not only how to refer patients when their problems are too complex for the personnel or resources available in their facility, but also how to help patients resolve their infertility when there is no treatment possible for whatever reason or treatment has failed. Following are strategies to enable health care providers to give the best possible care to refer patients or help them resolve their infertility.

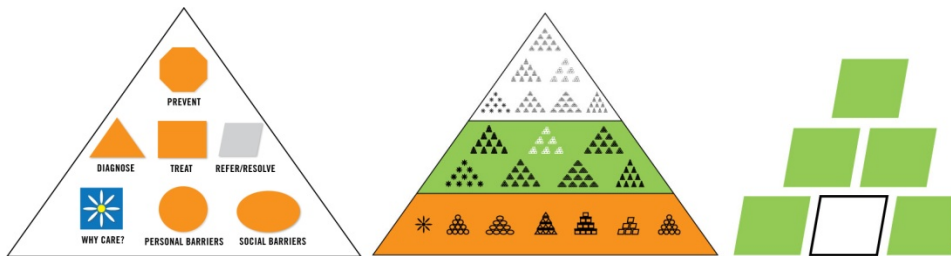


1. **Providers self-learn about referral resources, including adoption:** To facilitate referral, healthcare providers should educate themselves to be aware of the relevant components and resources of the healthcare system that can be used to prevent and manage fertility.

Healthcare providers should be knowledgeable of the resources that are available to them in their point of care and also elsewhere in the health system.

The rapidity in referring to the next level is dependent on the facilities that are available and the providers appropriate use of them.

A referral policy should be based on the facilities available in the point of care and also the healthcare structure. The effectiveness of these treatments should be known and used appropriately. Referral to the next level of care can then be made accordingly.



2. **Follow up treatment outcomes and reassess prognosis:** Determine appropriate follow-up intervals according to age, duration of infertility, patient clinical factors, patient socioeconomic / cultural factors and available infertility services.

Using an infertility score based on 6 parameters (age of female, duration of infertility, primary or secondary female infertility, percentage of motile sperm and referral status, the chances of subfertile couples conceiving can be prognosticated. (Hunault, 2004)

When the prognosis is poor, then referral should be made quickly.

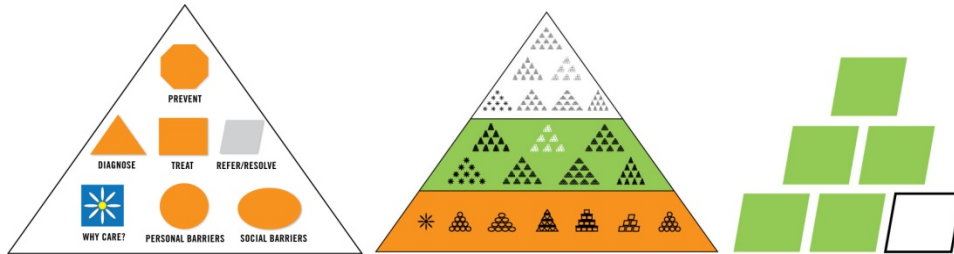
It is important not to waste time because the older the patient, the lower is the probability of success in fertility treatment.

Couples should be re-evaluated at reasonable intervals. At the appropriate time, a decision has to be made and a quick referral made.

If the prognosis is very poor and nothing more can be done, then consider closure counseling (see 6).

It is important to determine the relationship dynamics and social dynamics between the patient and her husband at regular intervals, which may be 3 – 6 months.

Clinicians should warn against treatments and cultural practices that may cause infertility or aggravate subfertility. It is their professional responsibility to guide patients away from these practices. (ESHRE Task Force on Ethics and Law, 2009)

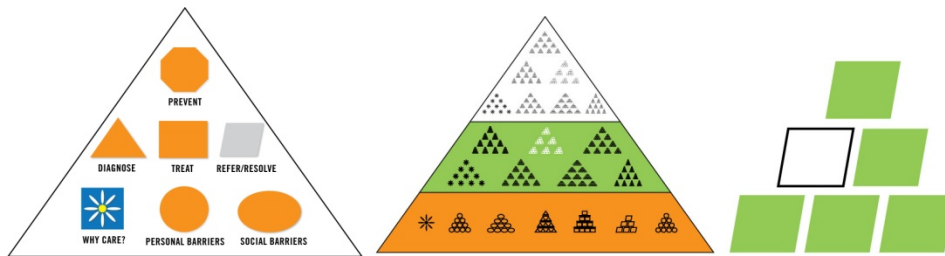


- 3. Perform ongoing assessment of self and fertility services:** To continually improve the services provided, infertility healthcare providers should
- Set up an on-going self-assessment for the services they are providing.
 - Evaluate their personal performance on a routine basis.
 - Assess the accessibility and quality of their services on a routine basis.
 - Continue to educate themselves so that they can provide improved services to as many patients as possible who will benefit from their care.

Healthcare providers should continually assess their own performance and also that of the health center. Healthcare providers should continually assess that they know:

- When to refer
- Where to refer
- When to stop

They should always aim to ask themselves “Did I do a good job given my limitations”.

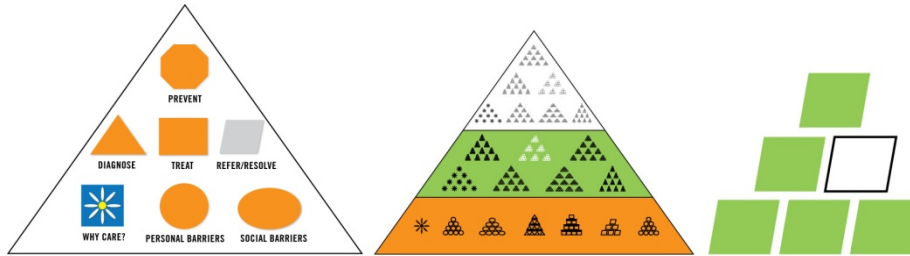


- 4. Refer for further fertility treatment:** Refer for further more specialized or sophisticated fertility treatment in the nearest / most accessible facility for the patient.

Healthcare providers should know where the nearest or most accessible facilities are.

The integration of family planning, fertility and maternal health services in well-organized existing or newly-created Reproductive Healthcare Centres fulfills the objective of supporting family planning programmes while providing treatment for the infertile couple (Ombelet, 2008)

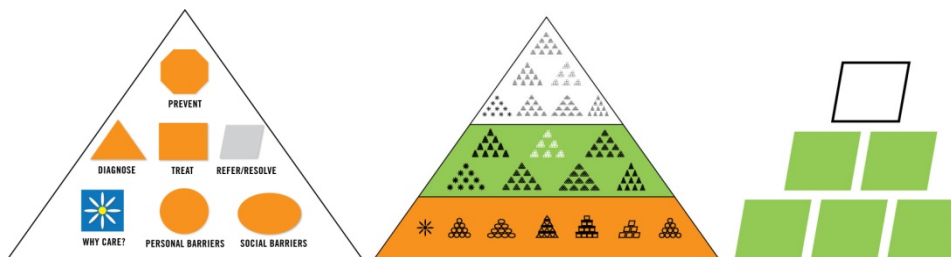
Clinicians tend to over-estimate the success outcome. They should have a realistic assessment of their chances of success. It is important to attempt to educate the patient on the meaning of real outcome i.e. an objective understanding of the outcome.



5. **Refer for management of other medical and social problems:**
 - a. Determine whether social services and marital counseling services are available and refer when indicated.
 - b. Refer for management of any co-existing medical conditions.

At each follow-up, the healthcare provider must take time to ask about the social history pertaining to the couple.

The healthcare provider must also ask about co-existing medical conditions at each follow-up visit and either provide management or refer for management.

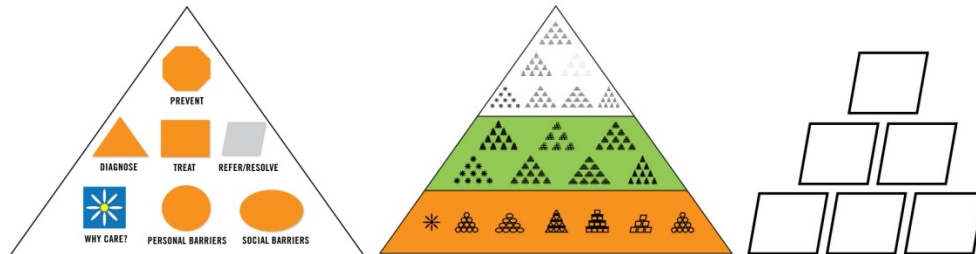


6. **Provide ethical closure counseling:** Understand the cultural aspects of infertility and its ethical considerations .To facilitate closure healthcare providers should
 - a. Recognize when closure counseling is needed.
 - b. Educate themselves to be aware of and evaluate available adoption services.

Cultural perspectives regarding infertility and ART are as diverse as the societies in which they exist. However, one common theme is that infertility is perceived universally by the infertile as a stigma. In many cultures infertility is usually blamed on the female partner. As a result, the burden of infertility is heavier for women, especially in societies that define womanhood through motherhood. The feeling of stigmatization is exacerbated by family, peer and media pressure leads to psychological, marital and social problems. (Daar, 2001)

Providers should ask patients about the impact of their infertility on their lives, and how their family and social system affects this. Using this information and the prognosis for the patient the provider can determine when hopeful expectation should be replaced by closure counseling. Other options for the patient, such as adoption or a more involved role with other children in the extended family, should be

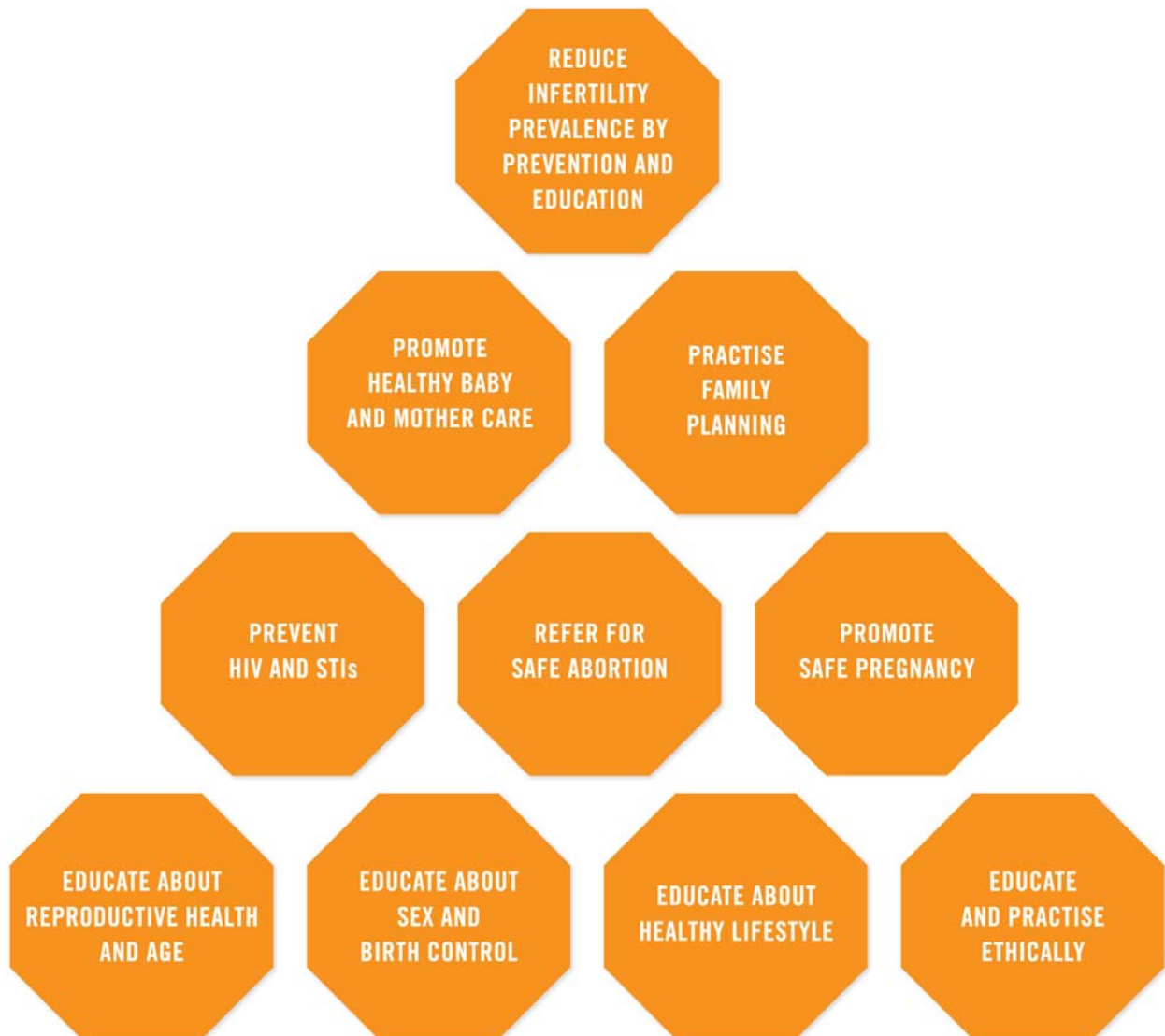
explored. In exceptional circumstances, depending on the patient's unique situation and the societal/cultural values and customs, it may be appropriate to discuss donor sperm, egg or embryo, surrogacy/gestational carrier or cross border reproductive care.



REFERENCE TOOL 6: HOW TO REFER AND/OR RESOLVE INFERTILITY REFERENCE

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THE FIGO FERTILITY TOOL 7: HOW TO PREVENT INFERTILITY



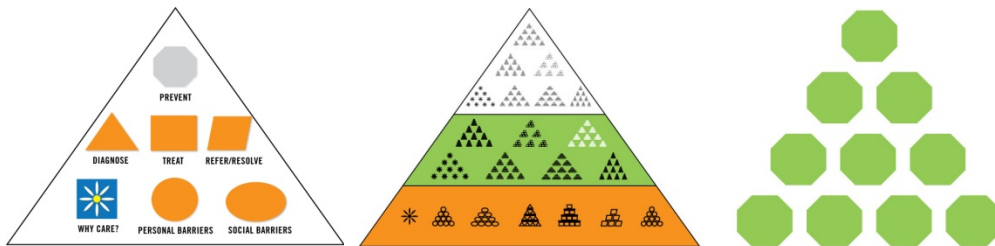
BASIC TOOL 7: **HOW TO PREVENT INFERTILITY**

1. **Educate about reproductive health and age:** There should be access for all to education about fertility and infertility and the reduction of female fertility with increasing age.

2. **Educate about sex and birth control:** Education about sexual physiology, sex practices, how pregnancy occurs and methods of birth control are important at an early age. With knowledge women can be empowered to increase their chances of preventing pregnancy that is at too young an age and/or is unwanted.
3. **Educate about healthy lifestyle:** Lifestyle factors such as smoking, under-nutrition, chronic high stress and obesity can substantially reduce fertility. Every educational approach to promote healthy living should clearly address the effect of lifestyle factors on fertility.
4. **Educate and practise ethically:** A critical and essential aspect of providing healthcare is to know how to and to practise ethically. This is often challenging, especially in reproductive medicine, because of different values and forces that are presented by society and its customs, patients themselves, and the healthcare provider.
5. **Prevent HIV and STIs:** HIV and other sexually transmitted infections are common, preventable causes of infertility. Professionals and other providers in fertility/infertility programs should identify and liaise with other professionals, providers and organizations that are involved in HIV and STI education and prevention to coordinate activities that help prevent the transmission of HIV and STIs.
6. **Refer for safe abortion:** Unsafe abortion can cause future infertility. Professionals and other providers in fertility/infertility programs should identify and liaise with other professionals, providers and organizations provide safe abortion to coordinate activities that help all women receive safe abortion services when needed.
7. **Promote safe pregnancy:** Every wanted, healthy baby born to a healthy mother consolidates a family and reduces unmet fertility desires. Professionals and other providers in fertility/infertility programs should identify and collaborate with other professionals, providers and organizations that promote safe pregnancy.
8. **Promote healthy baby and mother care:** Good neonatal care and healthy motherhood are cornerstones of reproductive health. They optimize current fertility and reduce the risk of future infertility and childlessness. Professionals and other providers in fertility/infertility programs should identify, support and collaborate with other professionals, providers, organisations and social services that enable and enhance neonatal care and healthy motherhood.
9. **Practice family planning:** Preventing unplanned pregnancies protects future fertility. It avoids the risk associated with any pregnancy and the risk of unsafe abortion. Barrier contraceptive methods protect against HIV infection and STIs. Education programs and social care systems should, from a young age, offer easy and accessible information on

the many benefits of preventing, planning (and spacing) pregnancies. Education that enables people to increase the chances of pregnancy when so desired and to prevent pregnancy when so desired should be included in health and education programs. Safe contraceptive methods should be available to all sexually active men and women.

- 10. Reduce infertility prevalence by prevention and education:** Infertility is largely preventable. General education and health care prevention strategies can substantially reduce the prevalence and burden of infertility which affects approximately 80 million women worldwide.

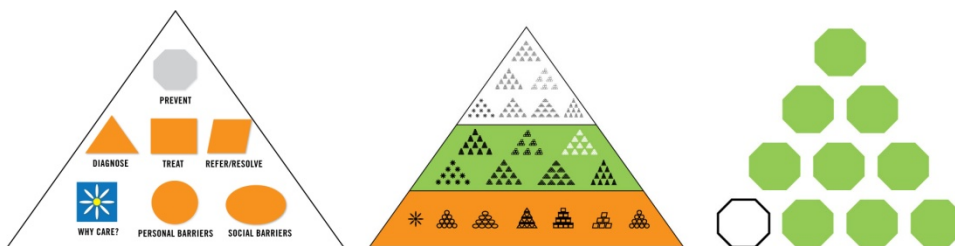


SUPPORT TOOL 7: HOW TO PREVENT INFERTILITY

General Comment

Prevention reduces or sometimes avoids the harm of infertility for some of the population at risk, even if some of those affected later have access to treatment. Prevention generally involves not only access to healthcare but also to health education. Additionally, prevention also often involves general societal measures to prevent infertility, such as improving general conditions like water supply and road transportation. Improvement of such general conditions can have a major impact on the care of pregnant women and prevention of secondary fertility.

Specific conditions related to reproductive health include promoting the use of condoms, counseling persons at high risk of transmitting and catching sexually transmitted diseases, training birth attendants to prevent post-partum infections, increasing access to safe abortions and decent maternity units, informing couples of the negative impacts of smoking and obesity, providing early treatment to people with sexually transmitted infections and so on. (ESHRE Task Force on Ethics and Law, 2009)



1. Educate about reproductive health and age: There should be access for all to education about fertility and infertility and the reduction of female fertility with increasing age.

This access to information should include all educational initiatives for reproductive health, and other health education programs as appropriate.

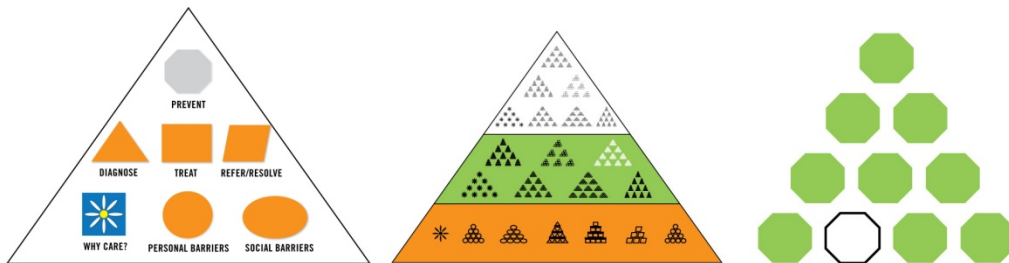
The WHO defines reproductive health as a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity in all matters relating to the reproductive system and to its functions and processes. This definition suggests that people with adequate reproductive health have a satisfying and safe sexual life, can have children, and can make a choice as to whether they would like to have children and if so, when and how to have them. Young people should be educated about the importance of reproductive health to the quality of their life.

This includes facts about male and female reproduction, enhancement of reproductive health through natural, medical and technology methods, and prevention of infertility.

Women and men should be educated about age and fertility. Educational programs should give clear basic information about the changes in fertility in relation to age, and the risks to women of postponing attempting conception until later in reproductive life, particularly after age 37. On the other hand, pregnancy in adolescent women (<19 years) can also produce circumstances that impact adversely on present and future fertility. (ACOG and ASRM, 2008; Dunson, 2004; Maheshwari, 2008; van Balen 1997;) Women should be told that female fertility generally begins to decrease around age 30, and some women become infertile because of decreased ovarian function in their early 30s. There are no clinical signs or tests that can provide assurance of normal ovarian reserve or predict the time of menopause in young women

Furthermore, as women age, the risk of miscarriage increases as does the risk of having a baby with an abnormality. Maternal morbidity and mortality also increase.

Male fertility also decreases with age, but much less and at an older age. There is also a slight increase in the risk of a birth defect and possibly some conditions such as autism.



2. Educate about sex and birth control: Education that enables people to increase the chances of pregnancy when so desired and to prevent pregnancy when so desired should be included in health and education programs.

Every educational opportunity in sexual health should have as part of the core objectives to provide basic information about maintaining a healthy sexual lifestyle. Particularly pertinent to

fertility is the timing of intercourse both to enhance and reduce the probability of pregnancy, and the use of birth control when not attempting pregnancy. (ASRM, 2008a)

The WHO defines sexual health as a personal sense of sexual wellbeing as well as the absence of disease, infections or illness associated with sexual behavior.

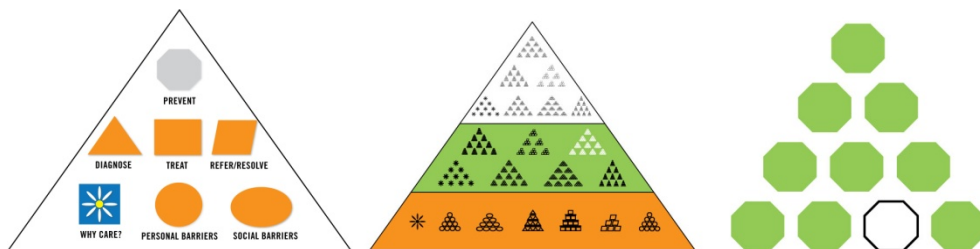
(http://whqlibdoc.who.int/hq/2000/WHO_MSD_MDP_00.14_Module4.pdf) It is important to educate young people regarding the benefits of delaying sexual activity consistent with cultural norms, the value of single partner relationships which carry less risk for STI/HIV and other disease transmission and the value of avoiding unwanted pregnancy.

Healthcare facilities, schools where appropriate, and other societal organizations should educate about the major methods of birth control, including condoms, oral contraceptives, IUDs and other methods.

Additionally, sex practices such as introducing herbs or other substances into the vagina to enhance male sexual pleasure with “dry sex” and other practices that result in mutilation, pain and/or reduced fertility and other problems should be discussed and their disadvantages explained to young people.

For couples attempting pregnancy, the best way to prevent infertility from a coital timing perspective is to have intercourse about 3 times per week, at the very least this frequency starting within a few days of the end of menses and lasting for two weeks or more.

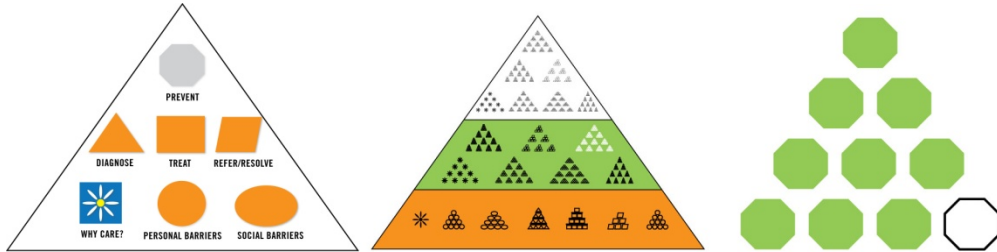
Lubricants such as KY jelly or Vaseline should not be used because they can interfere with sperm function. Canola vegetable oil is a good alternative, if necessary.



- 3. Educate about healthy lifestyle:** Lifestyle factors such as smoking, under-nutrition, chronic high stress and obesity can substantially reduce fertility. Every educational approach to promote healthy living should clearly address the effect of lifestyle factors on fertility.

This should have as a principle focus the benefits of eating well and also the short and long term harms of smoking on current and future reproductive and general health. (ASRM, 2008e; ASRM, 2008m; van der Steeg, 2008) Promotion of support, (e.g. smoking cessation programs) should sit alongside, enabling movement towards healthy living. (ASRM Practice Committee)

Schools and healthcare facilities should educate about healthy diets, unhealthy diets, weight control and the benefits and harms of eating well or not, both for current and future health.



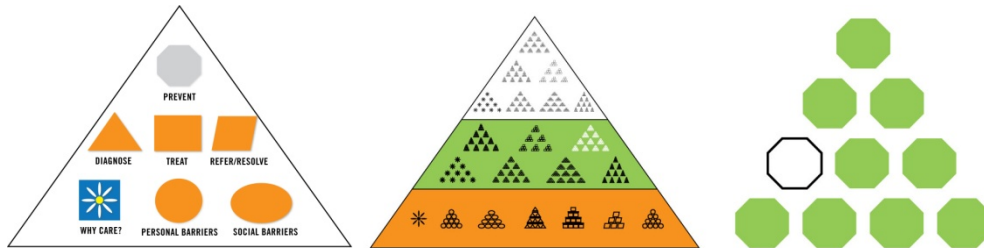
- 4. Educate and practise ethically:** A critical and essential aspect of providing healthcare is to know how to and to practise ethically. This is often challenging, especially in reproductive medicine, because of different values and forces that are presented by society and its customs, patients themselves, and the healthcare provider.

The International Federation of Obstetrics and Gynecology (FIGO), the American Society for Reproductive Medicine (ASRM), European Society for Human Reproduction and Embryology (ESHRE), World Health Organization (WHO), International Federation of Fertility Societies (IFFS) and others have documents that assist primary care providers and other clinicians in providing ethical care to their patients. (Organization References Recommended Reading: ASRM, 2012; ESHRE, 2012; FIGO, 2012; IFFS, 2012; IPPF, 2012; WHO, 2012). These documents should be used to assist PCPs and others when faced with difficult clinical situations.

PCPs and others, where appropriate, should be educated in simple terms regarding ethics, recognizing the societal frameworks in which they are providing care. The ethical principles of autonomy (patient independence), justice (societal fairness), non-maleficence (“do no harm”), and beneficence (“do good”) can be presented in simple terms to help providers in making decisions.

Ethical practice includes not overstimulating women during controlled ovarian stimulation, not treating patients for too long with treatments that are not working, diagnosing and managing properly endometriosis, myomas, ectopic pregnancy, not performing unnecessary surgery, not operation on varicoceles unnecessarily, not replacing too many embryos during ART procedures, preventing infections through vaccination and avoiding HIV transmission (ASRM, 2008b; ASRM, 2008i; ASRM, 2006b; ASRM, 2012a; ASRM, 2006a; Giudice, 2004; ASRM, 2008f; ASRM, 2008j; ASRM, 2008l; ASRM, 2012b; Min, 2010; ASRM, 2008h, ASRM, 2008g)

Providers should also be educated, within the societal framework, regarding their rights as providers.

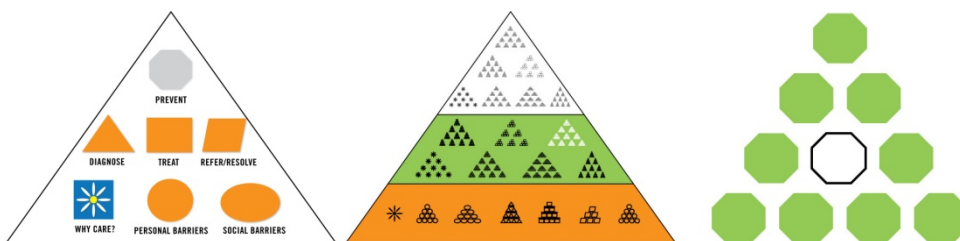


- 5. Prevent HIV and STIs:** HIV and other sexually transmitted infections are common, preventable causes of infertility. Professionals and other providers in fertility/infertility programs should identify and liaise with other professionals, providers and organizations that are involved in HIV and STI education and prevention to coordinate activities that help prevent the transmission of HIV and STIs.

HIV results in significant reproductive dysfunction, including increasing the risk of infertility, treatment of infertility, risk of pregnancy and childbirth and health of the child. Also, longer term illness in the mother and/or father may significantly compromise their ability to raise the child. Many programs exist to prevent, reduce and/or manage HIV in reproductive age patients. PCPs and other fertility providers should identify, support, and collaborate with, when possible, programs within FIGO and other organizations that promote the diagnosis and management of HIV.

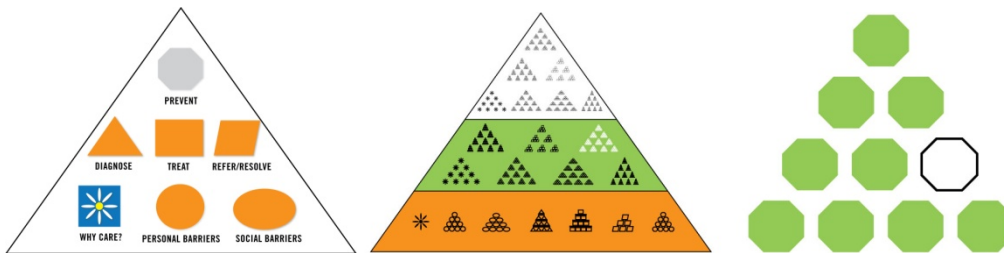
Numerous STIs, especially chlamydia trachomatis, gonorrhoea, streptococcus, and other infections can cause fallopian tube damage and pelvic adhesions. Tuberculosis can sometimes cause significant pelvic organ injury, including severe injury to the uterine cavity. (ASRM and SRSb, 2008; Mol, 1997)

PCPs and other fertility providers should identify, support, and collaborate with, when possible, programs within FIGO and other organizations that promote the diagnosis, treatment and prevention of STIs and tuberculosis.



- 6. Refer for safe abortion:** Unsafe abortion can cause future infertility. Professionals and other providers in fertility/infertility programs should identify and liaise with other professionals, providers and organizations provide safe abortion to coordinate activities that help all women receive safe abortion services when needed.

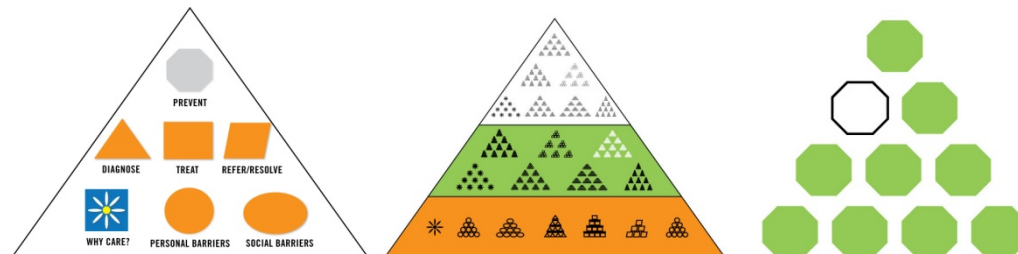
Elective abortion is a most difficult issue for many societies. Great differences in perspective exist in different cultures. Consistent with societal values and laws, it is important to promote and assist access to safe abortions for all women needing them. Safe abortions reduce maternal morbidity and mortality, and also reduce subsequent infertility and its associated personal and societal costs. (ASRM and SRSb, 2008)



- 7. Promote safe pregnancy:** Every wanted, healthy baby born to a healthy mother consolidates a family and reduces unmet fertility desires. Professionals and other providers in fertility/infertility programs should identify and collaborate with other professionals, providers and organizations that promote safe pregnancy.

Safe pregnancy results in healthier mothers and babies and less cost for society. A safe pregnancy and healthy baby provides the outcome desired by the woman and her family, reducing the need for additional attempts at pregnancy. Safe pregnancy reduces the risk of complications that could result in future infertility and need for treatment.

Professionals and providers should identify, support and refer to other providers and programs that promote safe pregnancy.



- 8. Promote healthy baby and mother care:** Good neonatal care and healthy motherhood are cornerstones of reproductive health. They optimize current fertility and reduce the risk of future infertility and childlessness. Professionals and other providers in fertility/infertility programs should identify, support and collaborate with other professionals, providers, organisations and social services that enable and enhance neonatal care and healthy motherhood.

Specific threats to babies include poor nutrition post-partum, inadequate health care, and inadequate mother and family situations.

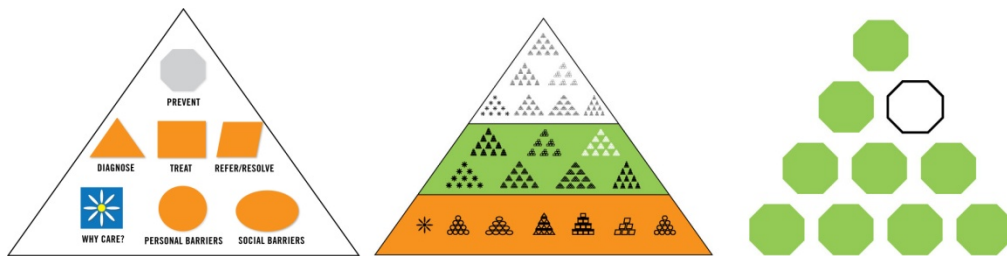
Specific threats to mothers include ongoing postpartum medical problems, postpartum depression, inadequate education, inadequate resources and problem family situations.

Childlessness, which can be perceived as infertility, can be the result of failure to conceive, miscarriage, stillbirth, neonatal death or childhood death. Therefore, it is important not just to get pregnant but to have a healthy child and family. All efforts that further this goal will result in reduced demand for additional children and therefore infertility.

Providers therefore need to identify, support and collaborate with referral sources that can help achieve the goal of a healthy baby and family. This includes helping establish good early childhood healthcare and care and support for the mother after she has delivered.

Infertile patients should be educated about these resources and their value in having a healthy family at the latest in the hospital after delivery.

For women who deliver at home this education and services can be provided when the baby is taken to a PCP for monitoring and follow up care.

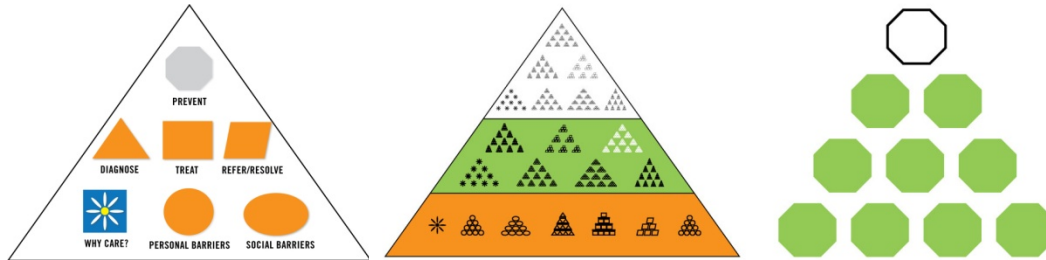


- 9. Practice family planning:** Preventing unplanned pregnancies protects future fertility. It avoids the risk associated with any pregnancy and the risk of unsafe abortion. Barrier contraceptive methods protect against HIV infection and STIs. Education programs and social care systems should, from a young age, offer easy and accessible information on the many benefits of preventing, planning (and spacing) pregnancies. Safe contraceptive methods should be available to all sexually active men and women.

Maternal mortality would be significantly reduced if women did not die as a result of unintended pregnancies. Unwanted pregnancies can give rise to unsafe abortions and other pregnancy-related complications which may compromise future fertility. Avoidance or delay of another pregnancy contributes to a healthier subsequent pregnancy, baby and mother.

Women should be educated in the hospital after delivery about the benefits of a longer interval between pregnancies and should have access to contraceptive programs that can help to ensure better contraception.

For women who deliver at home this education and services can be provided when the baby is taken to a PCP for monitoring and follow up care.



10. Reduce infertility prevalence by prevention and education: Infertility is largely preventable.

General education and health care prevention strategies can substantially reduce the prevalence and burden of infertility which affects approximately 80 million women worldwide.

Prevention of infertility is essential to reduce the prevalence of infertility. Successful strategies require recognition of the different causes, types and prevalence of infertility in urban and rural areas, and especially in different parts of the world. These differences require different actions to reduce the prevalence.

Education at all levels is the first step in prevention. Education is needed for women to create behavior change, for providers to create practice change, and for policy makers to create beneficial social policy. In the developing world infertility is commonly secondary and the result of STIs, puerperal infection or other disease. Education, programs and medical treatment to prevent these diseases are needed. In developed countries infertility is commonly associated with delayed childbearing. Education about reproductive health aging and better social support systems are needed to deal with these causes of infertility.

Provision of prevention services such as screening for STIs, antenatal programs and healthy motherhood programs should be a core component in health policy at all levels.

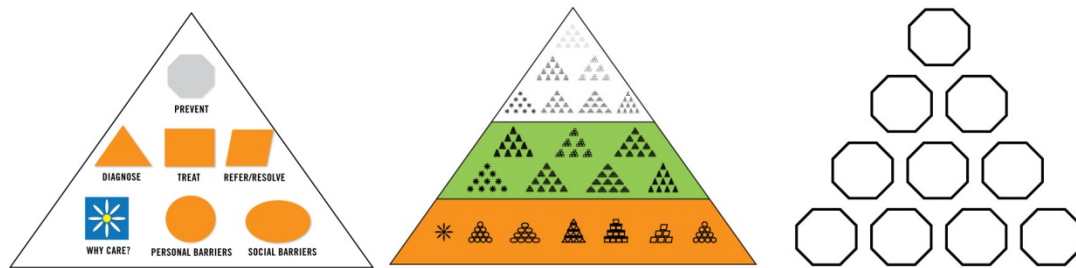
Professionals and other providers in fertility/infertility programs should enable and support implementation of education programs for the public, for providers and for policy makers. They can do this by making themselves aware of available resources. Resources include personnel, organizations, programs and financial resources. Where appropriate simple targets and indicators should be used to maintain clarity and focus so that progress can be measured.

In almost all countries of the world the major barrier to infertility care is cost. This is likely the most important barrier limiting access to safe and effective fertility treatment globally. The burden of infertility can only be reduced by increased social acceptance of the need to support infertility treatment financially either through government or private health plan.

The second major barrier to access to infertility diagnosis and treatment is ignorance of the general population about infertility, and the resultant lack of financial and societal support. This causes many

infertile people to suffer in emotional isolation without access to familial or societal understanding or support.

Therefore, it is imperative to provide public education and other programs that can help society understand infertility better. This requires that clear, accessible and consistent information about infertility be communicated to the media through professional groups. This is necessary to generate more support for the many actions that can help reduce the global burden of infertility.



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ORGANIZATION REFERENCES

*ASRM. American Society for Reproductive Medicine. www.asrm.org/EthicsReports/ Over 20 Ethics Committee Reports for healthcare professionals and other stakeholders.

*ASRM. American Society for Reproductive Medicine. www.asrm.org/Guidelines/. Over 50 Practice Guidelines written for healthcare professionals for all aspects of infertility and reproductive medicine.

*ASRM. American Society for Reproductive Medicine. www.reproductivefacts.org. Comprehensive information about all aspects of infertility and reproductive medicine written for the lay consumer.

*ESHRE. European Society for Human Reproduction and Embryology. www.eshre.eu/ESHRE/English/Guidelines-Legal/Guidelines/Archive/page.aspx/1520. Guidelines on infertility and assisted reproductive technologies.

*FIGO. International Federation of Gynecology and Obstetrics. www.figo.org. Comprehensive information about all aspects of gynecology and obstetrics from 124 national societies globally.

*ICMART/WHO Glossary. www.icmartivf.org/Glossary_2009_FertilSteril.pdf. Glossary on terminology used in infertility and ART.

*IFFS. International Federation of Fertility Societies. <http://www.iffs-reproduction.org/PracticeStandards.htm>. Practice Standards and Policy Statements regarding infertility.

*IPPF. International Planned Parenthood Foundation. www.ippf.org. Comprehensive information on IPPF activities.

*NICE. <http://www.nice.org.uk/nicemedia/pdf/CG011niceguideline.pdf>. Comprehensive guidelines from the United Kingdom on management of infertility.

*WHO. World Health Organization. <http://www.who.int/topics/infertility/en/>. Comprehensive information on WHO activities related to infertility, including WHO Laboratory Manual for the Examination and Processing of Human Semen.

AFA. The American Fertility Association. www.theafa.org. Comprehensive consumer information and support on infertility and family building.

ICMART. International Committee Monitoring Assisted Reproductive Technologies. www.icmartivf.org. Information on the practice of ART as reported by registries from 60 countries.

REDLARA. Red Latinoamericana de Reproduccion Asistida. http://www.redlara.com/aa_ingles/publicacoes.asp. Information on infertility and the practice of ART in Latin America.

RESOLVE. www.resolve.org. Comprehensive consumer information and support regarding infertility.

UNFPA. United Nations Population Fund. <https://www.unfpa.org/public/global/publications>
Comprehensive information on UNFPA activities.

***RECOMMENDED READING: References marked with an asterisk are considered to be especially valuable resources.**

Glossary of Terms

AIDS	acquired immunodeficiency syndrome
ART	assisted reproductive technology
ASPIRE	Asia Pacific Initiative on Reproduction
ASRM	American Society for Reproductive Medicine
CRM	Committee on Reproductive Medicine
ED	erectile dysfunction
ESHRE	European Society of Human Reproduction and Embryology
FIGO	International Federation of Gynecology and Obstetrics
FIGO CRM	International Federation of Gynecology and Obstetrics Committee on Reproductive Medicine
FSH	follicle stimulating hormone
GnRH	gonadotropin releasing hormone
hCG	human chorionic gonadotropin
HIV	human immunodeficiency syndrome
HP	health provider
HSG	hysterosalpingogram
ICI	intracervical insemination
ICMART	International Committee Monitoring Assisted Reproductive Technologies
ICSI	intra-cytoplasmic sperm injection
IFFS	International Federation of Fertility Societies
IPPF	International Planned Parenthood Federation
IU	international units
IUD	intra uterine device
IUI	intrauterine insemination
IVF	in-vitro fertilisation
LB	live birth
LH	luteinizing hormone
MDG	Millennium Development Goals
MRI	magnetic resonance imaging
NGOs	non-governmental organisations
OHSS	ovarian hyperstimulation syndrome
PCOS	polycystic ovarian syndrome
PCP	primary healthcare provider
PCT	post coital test
PHC	primary health care
QOL	quality of life
RHC	reproductive health clinic
Stakeholder	one who is involved in or affected by a course of action
STD	sexually transmitted disease
STI	sexually transmitted infection
THC	tertiary health care
WHO	World Health Organisation

ABOUT US



PROF. GAMAL SEROUR, MD, PHD, FIGO PRESIDENT 2009-2012

Professor Gamal Serour, MD, PhD, FIGO President 2009-2012 proposed The FIGO Committee on Reproductive Medicine (CRM) in 2009. President Serour asked David Adamson, MD, FRCSC (United States) to be Chair of this committee and Siladitya Bhattacharya, MD, PhD (United Kingdom) to be Co-Chair. After approval from the FIGO Board, the FIGO CRM was established with the following additional members: John Collins, MD (Canada), Klaus Diedrich, MD, PhD (Germany), Silke Dyer, MD, PhD (South Africa), Christine Robinson, MD (United Kingdom), Egbert te Velde, MD, PhD (Netherlands), PC Wong, MD (Singapore), Fernando Zegers-Hochschild, MD (Chile).

The FIGO CRM first met in London in March, 2010 to determine its vision, mission and strategic goals. This was done in detail and approved by the Executive Board of FIGO.

The initial major challenge was to determine what aspects of reproductive medicine the Committee would address. We defined reproductive medicine as the branch of medicine that uses medical, surgical, psychosocial and other interventions to help people maintain or improve their reproductive health. The Committee decided to focus on helping infertile women become pregnant and/or alleviating the burden of infertility. The Committee decided not to focus on Assisted Reproductive Technology (ART), but work within the range of generalist obstetricians and gynecologists and lower level healthcare providers, including lay providers and the public.

The concept of The FIGO Fertility Tool Box™ was developed and then expanded. We reviewed current policies and guidelines relevant to access, quality and evidence-linked reproductive care that were available at the World Health Organization (WHO), the European Society for Human Reproduction and Embryology (ESHRE), the American Society for Reproductive Medicine (ASRM), Latinoamericana de Reproducción Asistida (RED), the International Federation of Fertility Societies (IFFS) and other professional organisations, and also the literature. We identified a summary literature to educate Committee members on international sensitivities with respect to culture, religion, politics and economics.

Following this a great deal of work was performed by electronic communications, teleconferences, FIGO CRM meetings while attending professional association international congresses, and one annual 2 day meeting in London, England. The alpha version of The FIGO Fertility Tool Box™ is presented here.

This is an entirely new and novel instrument or ‘tool’ that is intended to be simple, usable, meaningful (i.e. provide value to users), multifaceted and evidence-linked. It is hoped that this tool will be used by many providers of women’s healthcare to increase access to quality, cost-effective infertility prevention and management.

The FIGO Fertility Tool Box is still in its early developmental stage; however, its principles and content have been agreed upon by the FIGO CRM. It must be emphasised that this is intended to be a very flexible and evolving instrument that will hopefully be applicable in very many different environments and countries and change with time and use.

It is hoped and expected that the FIGO CRM can continue to improve the Tool Box based on experience gained with its use. Furthermore, we hope that FIGO national obstetrics/gynecology organizations will identify novel ways to use The FIGO Fertility Tool Box in their countries. The FIGO CRM will work to expand awareness and use of the Tool Box globally.

In addition to the Tool box, our committee also began educating FIGO members about reproductive medicine, with the first postgraduate workshop being held in Cairo, 2010. The second meeting in Agra, India, in March 2011, enabled relationships to be established with the Federation of Obstetric and Gynaecological Societies of India (FOGSI) and the Indian Society for Assisted Reproduction (ISAR), and with academic and private physicians. A third workshop was held in Cairo in December 2011, and we will also participate in the FIGO 2012 Rome Congress.

The Committee has also developed a template to create and deliver better educational programmes, presented to the FIGO Committee for Capacity Building in Education and Training.

Relationships with other stakeholders in reproductive medicine have been established including the WHO, ESHRE, IFFS, ASRM, ICMART and the International Planned Parenthood Federation (IPPF). We look forward to increasing mutually beneficial working relationships with them, especially in the context of educational events.



G. DAVID ADAMSON, MD, FRCS, FACOG, FACS

G. David Adamson, MD, FRCS, FACOG, FACS is a reproductive endocrinologist, surgeon and Director of Fertility Physicians of Northern California. He completed his medical school and residency at the University of Toronto in Canada and his Reproductive Endocrinology and Infertility fellowship at Stanford University in Palo Alto, California. He holds clinical professorships at Stanford University and University of California, San Francisco. He is Past President of the American Society for Reproductive Medicine, AAGL, Society for Assisted Reproductive Technology, Society of Reproductive Surgeons, four other major gynecological societies, and currently Chair of the Committee on Reproductive Medicine for the International Federation of Gynecology and Obstetrics, Chair of the International Committee Monitoring ART, President of the World Endometriosis Research Foundation and Board member of the

International Federation of Fertility Societies. He is a member of over 20 professional societies including the American Gynecological and Obstetrical Society, Society for Gynecological Investigation and Society of Gynecological Surgeons. He has been an advisor, consultant, and reviewer to government, industry, professional, patient and non-profit organizations and has published and lectured extensively nationally and internationally on endometriosis, assisted reproductive technologies, reproductive surgery and infertility. He has been recognized as one of the best 400 physicians for women in America, the top 1% in his specialty by Best Doctors and by the World Health Organization as an expert in infertility. In 1997 he founded Advanced Reproductive Care, the largest physician national network company that provides financial programs and other services to IVF practices and their patients. In 2006 he received the Outstanding Achievement in Medicine award from the Santa Clara County Medical Society, and a Certificate of Special Congressional Recognition for outstanding and invaluable service to the community.



Prof. Siladitya Bhattacharya MBBS, MD (University of Aberdeen), FRCOG

Professor in Reproductive Medicine, University of Aberdeen and Honorary Consultant NHS Grampian
Current post: Head of Section of Applied Clinical Sciences, Division of Applied Health Sciences, School of Medicine and Dentistry, University of Aberdeen

SUMMARY OF EXPERIENCE

2008-present Head of Section, Applied Clinical Sciences, University of Aberdeen
Clinical Specialty Lead for Obstetrics & Gynaecology, University of Aberdeen
2006-present Professor of Reproductive Medicine, University of Aberdeen
2000 -2006 Senior Lecturer & Reader (Honorary Consultant), University of Aberdeen
1998-2005 Clinical Lecturer University of Aberdeen
1991 -1998 Various Registrar and Clinical Research Fellow posts in Kent, Leeds and Aberdeen
1984-1990 Various House Officer posts in India and UK

EDUCATION

1996 MD (University of Aberdeen)
1991 MRCOG (Royal College of Obstetricians & Gynaecologists)
1987 MBBS (University of Calcutta, India)

Research Interests: Health services research in reproductive health including randomised trials, epidemiology of reproductive failure and systematic reviews. Ongoing projects in infertility include randomized trials in infertility, systematic reviews, epidemiology of reproductive failure and patient preferences in fertility treatment. Other areas of interest include management of heavy menstrual

disorders and the effects of alternative modes of delivery on reproductive outcome and long term health in women.

External responsibilities:

- Member, Health Services Research Committee, Chief Scientist Office Scotland (2006 -)
- Member, Academic Committee, Royal College of Obstetricians & Gynaecologists (May 2007-)
- Chair: Reproductive Medicine Clinical Studies Group (RCOG) within the National Reproductive Health Research Network U.K.
- Deputy Chair: Reproductive Health and Childbirth Specialty Group (2009 -) U.K.
- Editor: Cochrane Collaboration, Menstrual Disorders and Subfertility Group (2004 -)
- Member: European IVF monitoring Committee (European Society for Human Reproduction and Embryology) (ESHRE) (2007 -)
- Member, Standards and Practice Committee for the International Federation of Fertility Societies IFFS (2007 -)
- Member, International federation of Obstetrics and Gynaecology (FIGO) Reproductive Medicine Committee (2009 -)

SELECTED PUBLICATIONS:

“Clomifene citrate or unstimulated intrauterine insemination compared with expectant management for unexplained infertility: pragmatic randomised controlled trial”. Bhattacharya S, Harrild K, Mollison J, Wordsworth S, Tay C, Harrold A, McQueen D, Lyall H, Johnston L, Burrage J, Grossett S, H Walton J Lynch A Johnston, S Kini, A Raja, A, Templeton. *BMJ* (2008); 337, 716

“Conventional in-vitro fertilisation versus intracytoplasmic sperm injection for the treatment of non-male factor infertility: a randomised controlled trial”. Bhattacharya S, Hamilton MPR, Shaaban M, et al. *Lancet*, (2001); 357: 2075-2079.

“The effect of B vitamins and genetics on success of in-vitro fertilisation: prospective cohort study.” Haggarty P, McCallum H, McBain H, Andrews K, Duthie S, McNeill G, Templeton A, Haites N, Bhattacharya S. *Lancet* 2006 6;367(9521):1513-9.

“Safety versus success in elective single embryo transfer: women’s preferences for outcomes of IVF” Scotland GS, McNamee P, Bhattacharya S. (2007) *BJOG* 114 (8): 977-983

“Inherited predisposition to spontaneous preterm delivery” Bhattacharya S, Raja EA, Ruiz-Mirazo E, Campbell D, Lee AJ, Norman J & Bhattacharya S. Jun-2010 In: *Obstetrics & Gynaecology*.

“Direct health services costs of providing assisted reproduction services in older women” Maheshwari A, Scotland GS, Bell JS, McTavish A, Hamilton M & Bhattacharya S. 15-Jan 2010 In; *Fertility & Sterility*. 93, 2, p.527-536.

“Interventions for ‘poor responders’ to controlled ovarian hyper stimulation (COH) in in-vitro fertilisation (IVF)” Pandian Z, McTavish AR, Aucott L, Hamilton MP, Bhattacharya S. *Cochrane Database Syst Rev* 2010 Jan 20; (1) CD004379

“Relationship between semen parameters and spontaneous pregnancy”. Sripada S, Townend J, Campbell D, Murdoch L, Mathers E, Bhattacharya S. *Fertil Steril*. 2009 Apr 8. [Epub ahead of print]



John Collins, MD, FRCSC, FRCOG, FACOG

John Collins is an obstetrician gynecologist and reproductive medicine specialist who worked in London, Halifax and Hamilton, Canada. He is Editor-in-Chief of Human Reproduction Update. Dr. Collins is a consultant member of the Practice Committee of the American Society for Reproductive Medicine, and a member of the Royal Belgian Academy of Medicine. He is a former President of the Society of Obstetricians and Gynecologists of Canada, the Canadian Fertility and Andrology Society and the Association of Professors of Obstetrics and Gynecology. His research involves more than 200 peer-reviewed papers on the effectiveness, safety and cost of interventions for reproductive health disorders and the long-term cardiovascular and cancer outcomes associated with use of oral contraception and hormone replacement.

treatment.



Prof. Dr. med. Klaus Hermann Rolf Diedrich

Education

- 1966: High school graduate at the Matthias-Claudius-Gymnasium in Hamburg
- 1966: Start of studies in human medicine at the University of Hamburg
- 1967: Naturwissenschaftliche Vorprüfung in Hamburg
- 1968: Ärztliche Vorprüfung
- 1972-73: Junior house officer in surgery and internal diseases
- 1973-74: Military service as M. D.
- 1974-78: Senior house officer in OB/GYN at the university clinic of Hamburg
- 1979: Consultant at the department of OB/GYN at the university clinic of Lübeck
- 1981: Ph. D. in Obstetrics and Gynecology

Professional Career

- 1984: First consultant at the department of OB/GYN of the

- university clinic of Bonn; University Professor
- 1984: Founding member of the European Society of Human Reproduction and Embryology (ESHRE)
- 1985-91: Secretary of the European Society of Human Reproduction and Embryology (ESHRE)
- 1991-93: Chairman-elect of the European Society of Human Reproduction and Embryology (ESHRE)
- 1993: Head of department of Obstetrics and Gynecology of the University Clinic of Lübeck
- 1993: President of the European Society of Human Reproduction and Embryology (ESHRE)
- 1994-2000: Secretary of the German Society of Obstetrics and Gynecology (DGGG)
- 2001: Member of the German Academy of Science Leopoldina
- 2000: Vicepresident (chairman-elect) of the German Society of Obstetrics and Gynecology (DGGG)
- 2002: President of the German Society of Obstetrics and Gynecology (DGGG)
- 2004: 2. Vicepresident of the German Society of Obstetrics and Gynecology (DGGG)
- 2006: Vice Dean of the University of Lübeck
- 2006: Fellow of the Royal College of Obstetrics and Gynecology
- 2006: Foundation of the German-Greek Society of Obstetrics and Gynecology by Prof. Agorastos (President) and Prof. Diedrich (Vizepresident)
- 2006: Medical Director of the University Hospital of Lübeck
- 2009: Doctor honoris causa of the Aristoteles University of Thessaloniki
- 2010: Medical director of the University Hospital Schleswig-Holstein, Campus Lübeck

Member of 18 national and international Editorialboards.
Publications: 480 in national and international journals



Silke J. Dyer, MBChB, MMed, PhD

Department of Obstetrics & Gynaecology
Groote Schuur Hospital and Faculty of Health Sciences, UCT
Cape Town, South Africa

Academic and Professional Qualifications

- 1985 MBChB University of Munich, Germany
- 1992 FCOG Colleges of Medicine of South Africa
Awarded Daubenton Medal as the candidate with the most outstanding achievement in the Fellowship examination
- 1993 Facharzt für Gynaekologie und Frauenheilkunde (German equivalent of FCOG), Luebeck, Germany
- 1997 MMed Title of thesis: "Strategies to improve artificial insemination by donor"
Supervisor: Prof ZM van der Spuy, Faculty of Health Sciences, University of Cape Town

- 2006 PhD Title of dissertation: "Infertility in the public health care system in South Africa: Patients' experiences, reproductive health knowledge and treatment-seeking behaviour".
Supervisor: Prof ZM van der Spuy, Faculty of Health Sciences, University of Cape Town
- 1988 Full registration, Medical Practitioner
- 1993 Specialist registration
- 2006 Subspecialist registration: Reproductive Medicine

Current Position

A/Professor, Deputy Head of Department and Head: Reproductive Medicine Unit
Department of Obstetrics and Gynaecology,
Faculty of Health Sciences, University of Cape Town

Societies: National and International Memberships

- 1997 – 2004 Member of South African Society of Medical Women
- 2000 - present Member of the South African Society of Reproductive Scientists and Surgeons
- 2001 - present Member of the South African Menopause Society
- 2002 - present Member of the European Society of Human Reproduction and Embryology; Member of the Taskforce: Infertility in Developing Countries.
- 2004 - present Member of the South African Society of Obstetricians and Gynaecologists

Offices Held

- 1997 - 2000 Chairperson: South African Society of Medical Women
- 2000 - present Committee member: South African Society of Reproductive Scientists and Surgeons; Chair: sub-committee ART data monitoring
- 2010 – present Committee member: Reproductive Medicine Committee of FIGO (International Federation of Obstetrics and Gynaecology)
- 2011 - Committee member: ICMART (International Committee Monitoring Assisted Reproductive Techniques)



Christine A. Robinson, MBBC, MA, MRCOG, MFSRH, FRCOG, FFSRH

Education

1979-1982 St Thomas' Hospital Medical School London
1976-1979 Cambridge University – Girton College
1969-1976 Bexley Grammar School

Qualifications: 1982 M.B B.Chir; 1983 MA (Cantab); 1990 M.R.C.O.G.;
1994 M.F.S.R.H.; 2003 F.R.C.O.G.; 2006 F.F.S.R.H.

Leadership Experience

- President of the Faculty of Sexual and Reproductive Health Care - FSRH)
NHS Board level (medical director and acting CEO)
- Board level experience: Chair of a national representative body for 3 years
Executive director of an NHS trust for 5 years (3 months as acting CEO)
- Negotiating skills: lead successful negotiations with Minister, MPs and national bodies
(Department of Health and others) in order to establish in 2010 the new medical
specialty of Community Sexual and Reproductive Health. This is the first time
that a medical sub-specialty has been built into a full specialty. There is no
equivalent anywhere else in Europe.
- Experience in change management: restructured the FSRH to facilitate its enhanced role in
leading a medical specialty and redesigned local clinical services and pathways.
- Relationship building: forged effective relationships with CEOs of national NHS organisations and
other groups (e.g. Family Planning Association) to harness shared views and
influence national policy.
- Excellent communication skills: extensive experience in liaising with the press and other media
and have managed the work of a professional communications firm.
- Achievements in education and standards: overseen the complete redevelopment of a new and
educationally cutting-edge National Diploma for Sexual and Reproductive
Healthcare, whose e-learning element won an e-government skills and
knowledge award. Also developed, promoted and delivered a number of
national standards of care in Sexual and Reproductive Health and successfully
established working groups with other national bodies responsible for clinical
standards to produce jointly used standards.
- International experience: member of the international advocacy group of the Royal College of
Obstetricians and Gynaecologists and of the reproductive medicine group of the
Federation of International Gynaecology and Obstetrics.

Current Roles

President , Faculty of Sexual and Reproductive Healthcare of the Royal College of Obstetricians and Gynaecologists June 2008-June 2011. Elected as President in 2008. The Faculty is a national, medical educational charity with 16,000 members.

Achievements in post: Established the new medical speciality of Community Sexual and Reproductive Healthcare (CSRH)

Transformed a professional qualification

Produced clinical standards

Produced national-evidence based clinical guidance

Established the SRH Clinical Studies Group of the National Reproductive Health Network

Enhanced International Profile

Enhanced media profile

Collaborative working

Consultant in Reproductive Health Southwark PCT

Clinical Private Practice

2007-current

Practice based at the Lister Hospital Chelsea and in Harley Street specialising in the reproductive health needs of women with breast cancer, contraception, medical gynaecology and menopausal medicine. Worked with hospital management and clinical colleagues to develop woman's health care packages and these services were launched in March 2011.

Previous Roles

Faculty Positions

Vice President

2005-2008

Honorary Secretary

2004-2005

Chair, Clinical Standards Committee

2003-2004

Co-authored four clinical standards

Medical Director, Bedfordshire and Luton Community NHS Trust

1998-2003

Consultant in Reproductive Health

1996-2003

Clinical Director of Sexual Health Services

1999-2002

Community and Acute Gynaecologist, London

1982-1996

Many publications in peer-reviewed journals

Lead and contributor to numerous NHS documents

National Bronze Clinical Excellence Award 2006

"Triple-blue" at Cambridge.

"Day Skipper" certificate, achieved in 2007.



E.R. te Velde MD, PhD

Egbert Rein te Velde was born in 1939 in Indonesia. In 1958 he started to study medicine in Amsterdam and got his medical degree in 1966. He went to Africa where he worked as a general doctor in rural mission hospitals until 1972.

He specialized in obstetrics and gynecology in the department of Obstetrics and Gynecology at the University Hospital Utrecht from 1972-1977.

He wrote a thesis entitled 'The clinical significance of tumor index substances and the assessment of immune competence in patients with cervical cancer'.

After the retirement of his tutor professor Jan Kremer in 1986, he became the head of the department of reproductive medicine and professor of Reproductive Medicine at the University of Utrecht in 1990. His inaugural lecture entitled, 'Becoming pregnant in the 21st century: ever later, ever more artificial' got much public attention. His message was that society more or less forces women to postpone motherhood to ages when they have become sub-fertile or even infertile.

He retired in 2004 when he gave a farewell lecture entitled 'Is women's emancipation still compatible with reproduction in the 21st century?' At that occasion he was assigned by the queen to become Knight in the Order of the Dutch Lion.

His main scientific interest was female reproductive ageing and prognostic models predicting the probability of a spontaneous pregnancy and of a pregnancy after Assisted Reproductive Technology. In several articles and lectures he expressed his concern about the increasing medicalization of the reproductive process, both in obstetrics and reproductive medicine. He published 180 articles and reviews in peer-reviewed international journals and supervised the scientific thesis of 24 medical doctors and epidemiologists.

Together with the sociologist Christien Brinkgreve, he wrote a book for lay people in Dutch entitled 'Wie wil er nog moeder worden?' ('Do women still want to become mother nowadays?') about the problems for mothers and children when delay child birth is delayed.



Professor P.C. Wong

FRCOG

Professor of Obstetrics & Gynaecology
Yong Loo Lin School of Medicine
National University of Singapore

Professor P.C. Wong is the Director of the Assisted Reproductive Technologies (ART) Programme in the National University Hospital. He is active in postgraduate education in the field of ART and has conducted and participated in numerous courses in the region. He was the first President of the Asia-Pacific Initiative on Reproduction (ASPIRE) from 2006 – 2008.

He is currently the Professor of Obstetrics & Gynaecology in the Yong Loo Lin School of Medicine and the Senior Consultant & Head of the Division of Reproductive Endocrinology & Infertility in the National University Hospital, Singapore. He is also the Director of the Centre for Reproductive Education & Specialist Training (CREST).



Fernando Zegers Hochschild, M.D

- Adjunct Professor (Agregado) of the Faculty of Medicine, University of Chile.
- Professor and Director of the Program of Ethics and Public Policies in Human Reproduction, University Diego Portales
- Doctor Honoris Causa by the University of Antofagasta, Chile.
- Founder (1983) and Director of the Unit of Reproductive Medicine at Clínica Las Condes Hospital until 2006. At present, senior staff member.
- Co-founder (1985) and member of the Board of Directors of the Chilean Institute of Reproductive Medicine (ICMER).
- Founder (1990) and executive director of the Latin American Registry of Assisted Reproduction (RLA).

- Founder (1995) and past President of the Latin American Network of Assisted Reproduction (REDLARA).
- Vice-chairman of the International Committee for Monitoring Assisted Reproductive Technologies (ICMART).
- Served as member of various scientific and ethic committees in the World Health Organization since 1984. At present, member of the Research Program Review Panel (RP2) of the Special Program of Research and Research Training in Human Reproduction (WHO/HRP).
- Appointed by the United Nations (2002) as medical expert to the Ad Hoc Committee for the initiation of the International Convention against the Reproductive Cloning of Human Beings.
- Appointed by the Inter American Court of Human Rights (2012) as independent expert for the case of Assisted Reproductive Technology in Costa Rica.
- Awarded with the “Clinical Science Award” by The European Society of Human Reproduction and Embryology (ESHRE) in Lyon, France (2007)
- Fellow of the American College of Obstetricians and Gynecologists (ACOG), USA. (2008).

Clinical activity is centered in the treatment of infertility with emphasis in modern reproductive technology. Global research interests include monitoring of regional and world trends in reproduction; and the influence of cultural diversity when confronting bioethical challenges in sexual and reproductive health.