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Better Healthcare Newsletter from Patrick Malone

For couples struggling with infertility, a 'gift of life' carries costs, burdens, and risks



Dear Jessica,

If some of your favorite couples seem down during this child-focused holiday season, go easy: Infertility is an increasing issue for Americans, affecting an estimated 1 in 8 couples who have trouble getting pregnant or sustaining a pregnancy.

IN THIS ISSUE

A scientific breakthrough became a common treatment in just a blink

State of ART: Questions and controversies rise, with need for more oversight

Ethical breaches at fertility care's frontiers

Where are the babies?

BY THE NUMBERS

8 million

Estimated number of babies born worldwide in four decades of in vitro fertilization technique

1 in 8

Number of couples who the federal Centers for

Child-bearing challenges can make even the most successful women and men anxious, depressed, and unhappy, as former First Lady Michelle Obama testified in her new autobiography.

And while medical science has made advances in assisted reproductive technologies, the treatments can be costly, invasive, burdensome (especially for women), and controversial. They're far from sure-fire, though they're prone, critics say, to excessively optimistic claims and too little oversight.

The gift of life, with medical assistance, puts would-be parents to formidable tests in hopes of joyous moments that some grown-ups may take for granted with their youngsters in the weeks ahead. A little seasonal perspective may help.

A scientific breakthrough became a common treatment in just a blink



Four decades have raced by since English biologist Robert G. Edwards and his gynecologist colleague Patrick Steptoe pioneered in vitro fertilization. It helped Lesley and George Brown with the birth of their daughter Louise Joy, now 40 and the world's first "test tube" baby. (The Bourne Hall Clinic photo above shows Edwards and the Browns).

The breakthrough IVF technique of mixing human eggs and sperm outside the body and then implanting the developing embryo back in the womb won Edwards the 2010 Nobel Prize in medicine.

It since has played a role in the births of an estimated 8 million babies worldwide and opened the door to the ever-growing medical field of assisted reproductive technology (ART), which describes an array of therapies that includes the donation, preservation, cultivation, and implantation of the germ cells that, under optimal circumstance,

Disease Control and Prevention estimate have trouble getting pregnant or sustaining a pregnancy

\$3.6 billion

Estimated value of U.S. market for fertility-related medical treatment

\$20,000

Estimated average cost of one 'cycle' (regimen) of IVF treatment. Most women undergo at least two cycles, meaning this infertility treatment's costs are just slightly less than average annual U.S. household income.

464

Number of clinics, centers, or programs nationwide offering IVF in 2015, according to the CDC

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[The Life You Save](#)

[Nine Steps to Finding the Best Medical Care — and Avoiding the Worst](#)

grow into babies. Besides IVF, some [patients benefit from IUI](#), a procedure that bypasses blockages in women's reproductive systems to inject healthy sperm directly into the uterus when they are ovulating. Others may undergo [intracytoplasmic sperm injection](#). ICSI, basically, involves extracting a single sperm to fertilize an egg, which then is allowed to develop somewhat before implantation in a woman's womb.

The [Catholic Church has opposed some of these therapies](#) for its faithful, but many other religions have embraced them. And as the [United States fertility rate hits new lows](#) (see below), the surprise about in vitro and other procedures may be how widely they're now used and how accepted they have become.

The federal Centers for Disease Control and Prevention in 2015 found [464 clinics nationwide](#) offering IVF and other forms of reproductive assistance, performing almost 232,000 cycles of ART annually, resulting in almost 73,000 living infants.

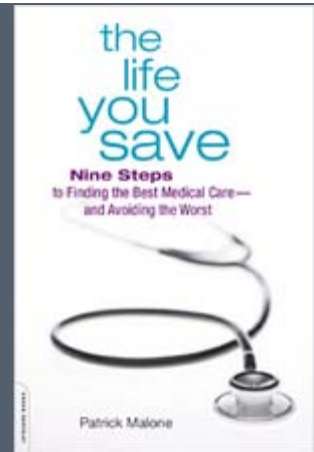
That's an accomplishment, considering the obstacles that couples must surmount as patients.

As Mrs. Obama described in *Becoming*, her recently published memoir, her saga started with a ["lonely, painful, and demoralizing" miscarriage](#). That loss of a pregnancy before 20 weeks is common and an experience that haunts many couples for a lifetime. It is little discussed, however. The former First Lady told ABC TV's Robin Roberts in an interview, "I felt like I failed, because I didn't know how common miscarriages were. Because we don't talk about them."

Mrs. Obama is [winning praise for her candor about the fertility challenges she shared with her husband](#), and their efforts to have children, with much of the heaviest lift to do so falling on her: Women who undergo IVF "cycles" or treatment regimens, and similar therapies must inject themselves with hormones, go in for daily ultrasounds and blood draws, and cancel work meetings to make room for clinic appointments.

The treatment also gets pricey, fast. A nonprofit called FertilityIQ collects voluntary data from ART participants nationwide, and the New York Times reported of its findings in 2017: "The cost of a single cycle of IVF is often about \$12,000, but that number is just a start. Drugs and related procedures, like genetic screening, push the average price in most major metropolitan areas to well above \$20,000 per cycle. ... And most couples undergo at least two cycles on average. ..."

Coverage for this care under health insurance or employee benefit



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Dispelling the silence and shame around suicide

programs varies greatly, [FertilityIQ notes on its website](#), reporting that help with reproductive treatment is “a tale of ‘haves and have nots,’ with 63 percent of patients and employees receiving zero coverage and almost 20 percent receiving complete coverage. Invariably, this is a function of what a patient’s employer is prepared to cover. While the number of U.S. companies offering an IVF benefit has grown by approximately 10 percent in 2017, as has the size of many employer’s benefits, this has not made a meaningful dent in the percentage of patients forced to pay for their care out of pocket.”

Infertility treatments — whether with IVF or other similar therapies, egg collection and freezing, or procedures using donors — may be reflecting deep divides in American society. They shouldn’t be, but they too often may be portrayed as the chief province of affluent, older, and white couples. This stereotype has been abetted by medical practitioners and operators of increasingly lucrative fertility programs and centers.

But that is just one of many downsides and controversies in what has become a medical industry, valued at \$3.6 billion in 2017 and, by some estimates, targeted to boom to \$4.5 billion by 2022.

State of ART: Questions and controversies rise -- and need for more oversight



[Ariana Eunjung Cha](#), a national reporter and onetime foreign correspondent for the Washington Post, has reported throughout 2018 on the fertility industry in a running series of excellent stories. Her work, referenced throughout this newsletter, paints a picture of a medical specialty that has managed to waltz through a public-policy mine field, burgeoning and mostly avoiding scandals and controversies that have plagued other reproductive health matters like abortion and birth control.

That does not mean that the field is problem free — far from it.

As it grows in complexity and reach, and as the numbers of its offspring grow and mature, assisted reproduction’s issues are

accumulating, as, for example, fertility experts collect and freeze women's eggs. The hope and plan here is to fertilize them later, allowing patients to time their child-raising to sync better with life, health, and career challenges. And medical scientists are working with men and women as sperm and egg donors, helping single would-be parents, notably women, and gay and lesbian couples, with new hopes and options in biological parenting.

But who is overseeing this exploding area of care? Lawmakers and bureaucrats, Cha has found, have steered away from doing so.

Instead, practitioners and providers, particularly specialist groups like the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology, have had wide room to “help” aspiring parents. This sometimes has left patients vulnerable — to excessive claims, deficient safeguards, and surprises that critics say could and should have been anticipated.

Would-be parents must slog through mountains of information about tests and procedures, insurance coverages, and more. They do so while juggling already hectic lives. And just how dedicated are busy fertility experts in providing them informed consent, their fundamental right to be told important facts so they can make intelligent decisions about what treatments to have and where to get it?

As Cha and others have reported, the issues that would-be parents and society itself may wish to consider include:

- Success rates. Although various centers and programs may promote their results, which can vary, as the Washington Post reported: “The overall success rate for having a child using one round of IVF in the United States is between 25 and 29 percent, according to the [Centers for Disease Control and Prevention]. ... Unsurprisingly, IVF success rates are linked to age. Women under 35 have the best chances of ultimately giving birth (43 percent). After age 37, success rates drop dramatically. Women ages 41-42 have only a 10 percent chance of IVF success, while women over 44 have only a 2 percent chance.” With assisted reproduction technologies, many patients harvest multiple eggs and fertilize them in each cycle, choosing to store embryos or implant multiples (see below). This creates further choices and challenges, including storage concerns and potential decisions if couples decide not to implant. They can donate the embryos to others or for research. They may choose to have them destroyed. These are daunting decisions and not without controversy.
- Genetic testing before implantation. As the technology for genetic testing grows more acute and accurate, would-be parents and fertility practitioners are confronting ever-more complex, difficult decisions. Prospective parents themselves undergo extensive exams, including genetic testing for

inheritable diseases and conditions, before starting ART. Embryos also can be gene-tested to see if they may carry evidence that a child may be born with a serious lifetime disease or condition, Stat, an online health and news site reported. But pre-implantation genetic testing (PGT) also can create what the site describes as an “ethical morass,” with patient decisions that may go from potentially knowing or deciding a prospective child’s sex to whether to advance the life of a baby that might have serious problems. Dr. Sigal Klipstein, a reproductive endocrinologist at InVia Fertility in the Chicago area, told Stat that patients’ choices may come down to this: “Would I rather have this baby with this disorder or no baby at all?” And while fertility experts are supposed to screen patients with great care even before they launch into treatments that may lead to in vitro procedures, [doctors can be poor readers and interpreters of test results](#). Practitioners also may struggle with their ethical responsibilities if patients, knowing of some potential risks, still wish to proceed with a possible pregnancy. The issue has become urgent enough that [a major practice group has issued a guidance on PGT and implantation decisions](#).

- Multiple births. Practitioners have adapted some of their techniques to reduce this risk. But [because patients often want to maximize their parenting chances](#), they may seek the implantation of more than one fertilized egg, [increasing the possibilities of a pregnancy with twins, many born prematurely and with accompanying health challenges](#).
- Myths about extended fertility. To be clear, [infertility isn't a women's problem](#): In a third of cases, the problem is with the man; in another third, it's with the woman; and in another third, the issue can't be identified, or it is a shared difficulty. But when age and careers matter, biology has handed women an unfair deal: Their fertility declines, often sharply, with age. And no matter the assertions of go-getters in finance, tech, or other high-powered occupations, [women have not seen medical advances that effectively extend their capacity to have children on a career-delayed schedule of their choice](#). Egg freezing may be booming, in the hope this might occur. But as the Washington Post reported: “The math doesn’t always hold up. On average, a woman freezing 10 eggs at age 36 has a 30 to 60 percent chance of having a baby with them, according to published studies. The odds are higher for younger women, but they drop precipitously for older women. They also go up with the number of eggs stored (as does the cost). But the chance of success varies so wildly by individual that reproductive specialists say it’s nearly impossible to predict the outcome based on aggregate data.” James A. Grifo, a fertility specialist at NYU Langone Health and a pioneer of egg freezing, told the newspaper that the

notion of women controlling their fertility — perpetuated by the media and embraced by feminists — is “destructive. It’s total fiction. It’s incorrect. Your whole life it’s beaten into your head that you’re in control and if you can’t have a baby, you blame yourself. There has to be more dialogue about what women can be responsible for and what they are not responsible for.”

- Storage calamities. In medicine, they’re called *never* events. They’re catastrophes so awful they’re *never* supposed to occur. In the fertility treatment world, however, not one but two of these calamities occurred this summer at the [University Hospitals Ahuja Medical Center’s Fertility Center in Cleveland](#) and the [Pacific Fertility Center in San Francisco](#). In both cases, breakdowns in advanced refrigeration equipment, which were purportedly monitored and maintained with rigor, led to patients losing thousands of frozen embryos and eggs. Affected patients are still sorting through their grief, even as lawmakers propose new regulations and lawsuits seek justice for those victimized. These twin incidents highlighted the mish-mash of oversight of fertility centers and programs. Fertility clinics are accredited by the pathologists’ college but operate under federal rules that are overseen by the Centers for Medicaid and Medicare Services (the Medicare/Medicaid overseer), the federal Food and Drug Administration, and, to some extent, the Centers for Disease Control and Prevention. States vary in their oversight of the facilities.
- Donor-offspring dilemmas. With decades of experience now and millions of progeny reaching into their middle ages, families, doctors, fertility centers, and growing numbers of men and women are grappling with [the roles donors have played in assisted reproduction](#). In especially painful cases, doctors have been exposed for having used their own sperm wrongly to impregnate patients seeking fertility care. In other cases, embryos have been switched before birth, babies were sired by the wrong father, and children have inherited serious, undisclosed medical issues. Instances of outright fraud, deceit, and criminality may be rare, experts say. But [unregulated practices also have resulted in individuals, later in their lives, discovering that they have dozens of genetic family members](#) — they are all related to prolific sperm and egg donors. Parents who participated in ART wrestle with how, how much, and when to tell their children about their biological start. The issue is complicated by a lack of effort and interest by U.S. regulators and lawmakers to step in and deal with typically anonymous egg and sperm donations. The process is often shrouded in privacy rules that protect donors but also keep their offspring from crucial information they may need about their own lives and health, especially as they decide to start their own families. Some donors have sought to elude tracking, changing identities and moving often. As genetic testing and

online databases proliferate, however, family secrets are being revealed. One online site, [the Donor Sibling Registry](#), says [thousands view its materials and sign in each month](#), in hopes of learning more about their genetic pasts and possibly determining and meeting their biological kin. Some young people are memorizing their donor numbers, and, as they get serious in relationships, are discussing with potential partners whether they are ART offspring, too. These efforts are designed to deter serious genetic consequences that might result from inadvertent pairings of related individuals.

How brave a new world are we in already with human reproduction and ways we can assist it? More frontiers will be tested and breached (see sidebar below). Meantime, though, we can't lose sight of our humanity in dealing with not just technologies but also with the real people — family members, friends, neighbors, work colleagues, and more — who struggle with fertility and child-bearing issues.

[Resolve](#), a nonprofit that also calls itself the [National Infertility Association](#), offers [sound counsel](#) on its website, about both child rearing in general and dealing with the holidays. The organization underscores that medical science, at its best, aims to enhance rather than to limit choices: Some of us want kids, others do not. That's a private, personal decision. It's not for others to probe or question. So, too, are potential parents' decisions to consider adoption options.

As for those who struggle to get and stay pregnant, they deserve privacy and respect. The group urges them to pick freely and easily whether to attend or to skip seasonal events, including family and work parties, that will be filled with children and pregnant moms, or that have too-poignant emphases on kids. If aspiring parents want to hit such parties or dinners, they should be prepared to answer well-intended but intrusive comments or questions and to deal with feelings that may well up.

Meantime, my seasonal cheer is already building: Here's hoping the holidays bring you and yours great health and much happiness. We can see and share the special joy that little ones discover in sacred, reverent, and rare moments when we hope the world slows and we think a lot more about each other. That can be a heart-warming experience for all of us across the ages, of course. Please be safe and well, don't overdo it (with all of it, including eating, drinking, driving, merry making, traveling and etc.). Here's to a great, healthful 2019!

***Ethical breaches
at fertility care's frontiers***

Where are the babies?



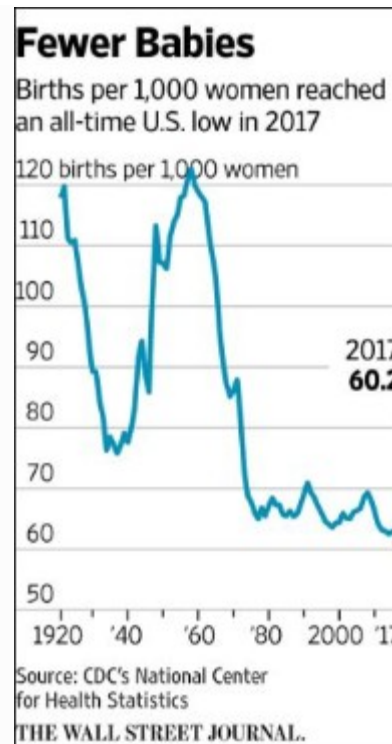
Ethicists and medical scientists around the globe have reacted with shock and fury to the announcement by a Chinese researcher that he broke accepted protocols to create the world's first genetically edited babies, twin girls who were born in November.

He Jiankui, who has studied at Rice and Stanford universities and now lives and works in Shenzhen, China, has provided no evidence and has not published any information on his claim that he used a powerful new gene-editing tool called CRISPR on human embryos, possibly including yet another baby on the way.

He (shown in photo above from a YouTube video he posted earlier) has asserted he did so, as part of an in vitro fertilization procedure, to ensure that a volunteer Chinese woman's children would have protection against HIV-AIDS. That disease is highly stigmatized in China and authorities have struggled to treat it.

More than 100 Chinese scientists issued a statement calling He's actions "crazy," and his claims "a huge blow to the global reputation and development of Chinese science." American scientists have denounced his genetic experimentation, and Rice has launched an investigation into a staffer who may have assisted He. Authorities have moved to shut down human gene-editing experimentation in China.

Experts long have known that editing of the genes of human embryos not only is possible but likely. U.S. officials have made it illegal to do so. Scientists fear that until much more is known



What's happening across the industrial world, but especially in the United States, is becoming a big concern for politicians, policy makers, economists, commentators, and futurists. That's because fertility rates are plunging, and Americans are having fewer children than even those they say they want.

As the New York Times reported: "The latest data from the Centers for Disease Control and Prevention, reflecting births as of the year ending in September 2017, shows the total fertility rate at 1.77 lifetime births per woman, down 3.8 percent since 2015, and down 16.4 percent since its most recent peak at 2.12 in 2007. (The replacement rate in developed countries is around 2.1.) The total fertility rate is a measure of how many children a woman entering her reproductive years today could expect to have, if age-specific fertility rates remain constant over time. In other words, it's a very simplistic forecast of lifetime births."

The nation's future depends on couples providing a steady supply of children who grow up, fill jobs, become economically productive, and support America and its elders, experts say.

But younger Americans, in their peak child-producing years, aren't marrying and choosing to have children as they once did, or they are doing so when older. They are having fewer kids. They also are living longer with their parents (even as

about such procedures and their long-term outcomes, genetic editing may pose [major health risks](#) and [giant ethical concerns](#).

Will, for example, powerful and wealthy parents try to perfect their progeny, demanding fertility and genetic experts modify babies in vitro or in utero for enhanced intellectual, artistic, or physical characteristics? Will experts tinker with genes and produce youngsters with devastating disease or debilitating conditions? Will experimentation result in destructive, unforeseen consequences for individuals, specific groups, or even all of humanity?

He's gene edits, if they occurred, have upset scientists because they appear to be of low value. Drugs are available now to treat HIV-AIDS, and doctors know ways to prevent infection and reduce maternal transmission. If a CRISPR experiment like He's were to get a green light in a serious, rigorous research institution, it would target a disease or condition for which medical science now has little remedy.

He, by the way, is not the only Chinese expert to challenge the scientific frontier of fertility treatment and genetic editing.

As the Washington Post reported, [John Zhang, the Chinese-born, British-educated founder and medical director of a Manhattan fertility center, came under regulators' fire](#) for helping "a 49-year-old patient ... carry her own child. In the not-too-distant future, he says, 60-year-old women will be able to do the same. In 2015, Zhang stunned his scientific peers by transferring a genetically 'abnormal' embryo to the womb of a woman who had run out of other options. Abnormal embryos — which appear to have the wrong number of chromosomes — are almost universally considered nonviable and discarded by other fertility doctors. The woman gave birth to a healthy baby girl, prompting clinics around the world to reevaluate their policies."

Federal officials stepped in and stopped Zhang, however, after he extracted non-disease-carrying DNA from a patient with a heritable neurological disease, injected it into the egg of healthy woman and fertilized it with sperm from the first woman's husband. The "three-parent" boy who was born from this procedure is healthy and free from neurological disease. But Uncle Sam has

the economy has boomed) and they are [having less sex](#). The nation's [recording fewer abortions](#). And, even when older, [more of us are choosing to forgo kids](#). With no regrets.

Fertility rates also have declined in France, Britain, and Norway. The world continues to watch Japan, as one of the world's major economies struggles with a plummeting birth rate and a gray, gray population.

What's going on? [As the Washington Post reported:](#)

"Economist [Lyman Stone](#) has blamed the United States' less-than-generous parental leave and pay policies. [Human Life International](#), a missionary group, blames 'pro-abortion population control groups like Planned Parenthood.' [Fox News pundit] Tucker Carlson claims it has to do with immigration, arguing that immigrants drive wages down, which hurts the attractiveness of men as potential spouses — 'thus reducing fertility.' Some have even wondered whether the [decline might be influenced by sperm quality](#). Recent medical journal publications have indicated that exposure to pollutants might be harming reproductive health, including the motility and quantity of sperm, which could delay childbearing and overall fertility. The University of Pennsylvania's Hans-Peter Kohler, who studies fertility and birthrates, said the data indicated that many shifts affecting fertility are occurring 'in the transition to adulthood.' The biggest recent drops in birthrate have been among teenagers as well as people in their 20s. In 2016, the teen birthrate hit at an all-time low after peaking in 1991."

Will hard-liners change their views about immigration as there are fewer U.S.-born young people to step up to jobs, especially in care-giving roles for the old, sick, and disabled?

Will corporate America make a radical shift in how it treats women in the workforce, opening not only more opportunities but also dealing, for real, with challenges in work-life balance?

Will the nation reverse course and provide more financial and other kinds of support for couples who pursue costly, invasive assistive reproductive technologies?

shut down Zhang from performing and marketing this procedure, saying it was barred human experimentation.

Recent Health Care Blog Posts

Here are some recent posts on our patient safety blog that might interest you:

- If patients weren't already unhappy with drive-by medicine, in which clinicians spend on average of 15 minutes with them in an office visit, [safety experts warn that too many doctors' providing of harried care can worsen a medical menace that's already hard to ignore: misdiagnosis](#). Figuring out what ails a patient and taking a correct course of action already is a "complex, collaborative activity that involves clinical reasoning and information gathering," reports Liz Seegert, a seasoned health journalist and a senior fellow at the Center for Health Policy and Media Engagement at George Washington University. But, in a briefing posted online for her journalistic colleagues, she goes on to amass some eyebrow-raising information on diagnostic errors, their frequency, harms to patients, and why experts in the field see corrections in this area needed, stat.
- Women may need to double-up on their consultations with their specialists about treatment for serious gynecological concerns, as new studies have raised [troubling questions about a much-touted minimally invasive surgery for early-stage cervical cancer](#). These concerns, in a more perfect world, also would prompt greater questioning and oversight by doctors, hospitals, regulators, and lawmakers of surgical "innovations."
- The National Hockey League, with its new settlement of claims on head injuries, has done the sport and its most important component — players, past, present, and future — no service. Instead, the game's leaders have [shown a disregard for factual medical science, and an excess appreciation for profits over people](#). In contrast to the \$1-billion concussion accord between the National Football League and its players, the NHL deal is parsimonious, amounting to \$19 million or so.
- With the nation's road toll rising in already alarming fashion, [Uncle Sam may need to step up information campaigns and even reconsider regulation of a greater than believed vehicle risk: aged and decaying tires](#). FairWarning, an independent investigative news site, and road safety advocates deserve credit for dogging the National Highway Traffic Safety Administration (NHTSA) about its tire-related crash data. That information, which plays a key role for policy- and law-makers in determining road safety measures nationwide, quietly got updated by federal bureaucrats. Their posted numbers suddenly indicated for

2015 that fatal tire-related crashes more than trebled from a standing figure of 200 to 719 such deaths, FairWarning and others found.

- Foolishness about food and its health effects can run not only into the negative — the sky will fall if you even nibble on meat, butter, or eggs! — but also into extremes about its purported benefits. Which is why, as recent news reports indicate, [skepticism and care](#) need to be exercised about probiotics, so-called “super foods,” and, yes, once again, the supposed virtues of organic produce.

**Don't miss out, by the way, on an important way to protect your health and that of your loved ones: Don't neglect those key deadlines for you to [make crucial decisions](#) about your health insurance coverage. If you qualify for Obamacare assistance, better act fast, starting by going to [healthcare.gov](#) [click here].*

HERE'S TO A HEALTHY 2019!

Sincerely,

A handwritten signature in black ink that reads "Patrick Malone". The signature is fluid and cursive, with the first letter 'P' being particularly large and stylized.

Patrick Malone

Patrick Malone & Associates

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