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or contact
John Robbins 281-965-6390
Jun Gai 281-498-4310

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Make Today Different
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Publisher: Wea H. Lee
President: Catherine Lee
Editor: John Robbins

Address: 11122 Bellaire Blvd., Houston, TX 77072
E-mail: News@scdaily.com

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Inside C2

Sunday, December 13, 2020

UK to refine allergy warning on Pfizer vaccine sparked by two adverse reactions

George Dyer, 90, receives the first Pfizer/BioNTech COVID-19 vaccine, administered by General manager of Covid Recovery Becky Board, at Croydon's University Hospital, on the first day of the largest immunisation programme

LONDON (Reuters) - Britain's medicine regulator warned people with significant allergies not to get Pfizer-BioNTech's COVID-19 vaccine after two people suffered adverse reactions, but was set to give more detailed guidance on Wednesday based on reviews of those cases.
George Dyer, 90, receives the first Pfizer/BioNTech COVID-19 vaccine, administered by General manager of Covid Recovery Becky Board, at Croydon's University Hospital, on the first day of the largest immunisation programme in the British history, in London, Britain December 8, 2020. Dan Charity/Pool via REUTERS
Starting with the elderly and frontline workers, Britain began mass vaccinating its population on Tuesday, part of a global drive that poses one of the biggest logistical challenges in peacetime history.

National Health Service medical director Stephen Powis said the advice had been changed as a precaution after two NHS workers reported anaphylactoid reactions from the vaccine.

"Two people with a history of significant allergic reactions responded adversely yesterday," Powis said. "Both are recovering well."

The Medicines and Healthcare Products Regulatory Agency (MHRA) initially advised anyone with "a history of a significant allergic reaction to a vaccine, medicine or food" to avoid taking the vaccine.

However, by the end of Wednesday that guidance was set to be refined after discussions with experts on the nature of the reactions.
"We're tweaking advice to make it very clear that if you've got a food allergy, you're not more at risk," Imperial College London's Paul Turner, an expert in allergy and immunology who has been advising the MHRA on their revised guidance, told Reuters.

Pfizer and BioNTech said they were supporting the MHRA's investigation.

Last week Britain's MHRA became the first in the world to approve the vaccine, developed by Germany's BioNTech and Pfizer, while the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) continue to assess the data.

A top U.S. official said on Wednesday that Americans with known severe allergic reactions may not be candidates for Pfizer's COVID-19 vaccine until more was understood about what had happened.

Canada's health ministry said it would look at the reported adverse reactions in Britain, but said adverse events were to be expected and would not necessarily change the risk/benefit of the shot, after the country approved the vaccine.

RELATED COVERAGE

UK medicine regulator examining Pfizer vaccine reactions as matter of priority
ALLERGIC REACTION
MHRA Chief Executive June Raine told lawmakers such allergic reactions had not been a feature of the Pfizer's clinical trials.

Pfizer has said people with a history of severe adverse allergic reactions to vaccines or the candidate's ingredients were excluded from their late stage trials, which is reflected in the MHRA's emergency approval protocol.

However, the allergic reactions may have been caused by a component of Pfizer's vaccine called polyethylene glycol, or PEG, which helps stabilise the shot and is not in other types of vaccines.

Imperial College London's Turner said: "As we've had more information through, the initial concern that maybe it affects everyone with allergies is not true.

"The ingredients like PEG which we think might be responsible for the reactions are not related to things which can cause food allergy. Likewise, people with a known allergy to just one medicine should not be at risk," Turner told Reuters.

The EMA said in an email that all quality, safety and efficacy data would be taken into account in assessing the vaccine, including data generated outside the EU.

In the United States, the FDA released documents on Tuesday in preparation for an advisory committee meeting on Thursday, saying the Pfizer vaccine's efficacy and safety data met its expectations for authorization.
The briefing documents said 0.63% of people in the vaccine group and 0.51% in the placebo group reported possible allergic reactions in trials, which Peter Openshaw, professor of experimental medicine at Imperial College London, said was a very small number.

"The fact that we know so soon about these two allergic reactions and that the regulator has acted on this to issue precautionary advice shows that this monitoring system is working well," he said.

However, Gregory Poland, a virologist and vaccine researcher with the Mayo Clinic in Rochester, Minnesota, said that the MHRA and NHS had overreacted initially.

"I would not have broadened to the degree they did," he said.

"It's reasonable to let the world know about this, and to be aware of it in terms of people who have had reactions like this to vaccines. I think to say medicines, foods or any other allergies is past the boundary of science."

WEA LEE'S GLOBAL NOTES

CORONAVIRUS DIARY

12/12/2020

Wealee@scdaily.com

America Is In Hell

The United States reported 108,044 COVID–19 hospitalizations on Friday, setting the highest record since the pandemic began. This is the tenth consecutive day that the U.S. has remained above 100,000 hospitalizations.

Today in Washington, D.C. President Trump signed a one–week stopgap funding bill to avert a government shutdown at midnight.

The Supreme Court today rejected a bid from Texas's attorney general supported by Trump to block the ballots of millions of voters in the battleground states that went in favor of president–elect Joe Biden.

On Wednesday Biden's son Hunter was under tax investigation, but federal prosecutors in Delaware now are looking into his dealings with a Chinese businessman.

White House Chief of Staff Mark Meadows today told FDA chief Dr. Stephen M. Hahn that a vaccine must be authorized by Friday or he needs to resign.

We are very sad to see what is going on around the nation. Many people are losing their lives to the COVID–19 virus and we still don't see any measures being put into place to slow down the pandemic. Our only hope now is the vaccine.

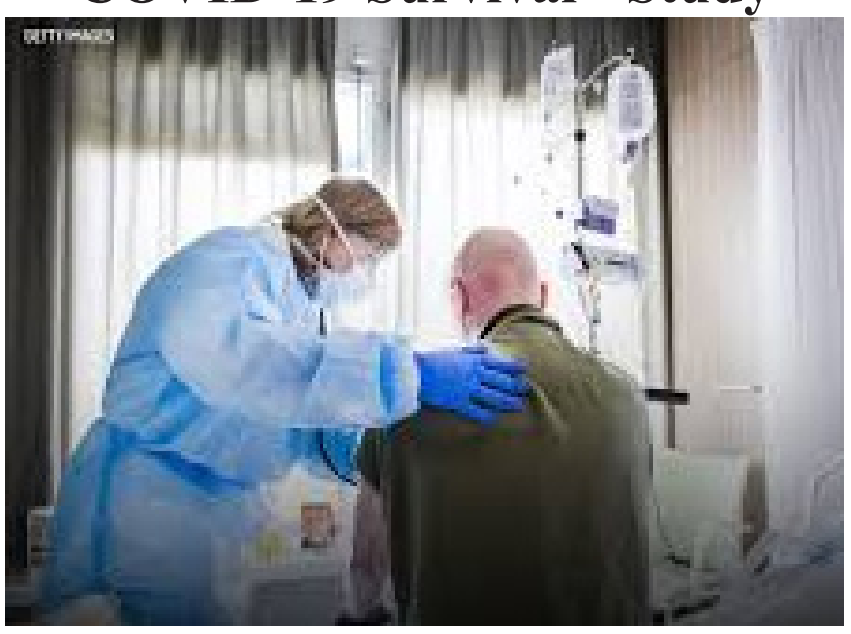
Southern News Group Chairman / CEO
Chairman of International Trade & Culture Center
Chairman of International District Houston Texas

Publisher Southern Daily Wea H. Lee

Stay Home! **BUSINESS** *Wear Mask!*

Reduces Death Rates Among Patients With Severe Cases

Common Steroid Improves COVID-19 Survival - Study



Compiled And Edited By John T. Robbins, Southern Daily Editor

A cheap, readily available steroid drug reduced deaths by a third in patients hospitalized with Covid-19 in a large study, the first time a therapy has been shown to possibly improve the odds of survival with the condition in the sickest patients.

Full data from the study have not been published or subjected to scientific scrutiny. But outside experts on Tuesday immediately embraced the top-line results. The drug, dexamethasone, is widely available and is used to treat conditions including rheumatoid arthritis, asthma, and some cancers.

In a statement, Patrick Vallance, the U.K. government's chief scientific adviser, called the result "tremendous news" and "a ground-breaking development in our fight against the disease."

Scott Gottlieb, a former commissioner of the U.S. Food and Drug Administration, called it "a very positive finding" in an interview on CNBC. "I think it needs to be validated, but it certainly suggests that this could be beneficial in this setting."

Related

Atul Gawande, the surgeon, writer and public health researcher, urged caution, tweeting, "after all the retractions and walk backs, it is unacceptable to tout study results by press release without releasing the paper."

The study randomly assigned 2,104 patients to receive six milligrams of dexamethasone once a day, by mouth or intravenous injection. These were compared to 4,321 patients assigned to receive usual care alone.

In patients who needed to be on a ventilator, dexamethasone reduced the death rate by 35%, meaning that doctors would prevent one death by treating eight ventilated patients. In those who needed oxygen but were not ventilated, the death rate was reduced 20%, meaning doctors would need to treat 25 patients to save one life. Both results were statistically significant.

There was no benefit in patients who didn't require any oxygen. The researchers running the study, called RECOVERY, decided to stop enrolling patients on dexamethasone on June 8 because they believed they had enough data to get a clear result.

"Dexamethasone is the first drug to be shown to improve survival in COVID-19," Peter Horby, one of the lead investigators of the study and a professor in the Nuffield Department of Medicine at the University of Oxford, said in a statement. He added that the drug should now become the standard treatment for patients with Covid-19 who need oxygen. "Dexamethasone is inexpensive, on the shelf, and can be used immediately to save lives worldwide.'"

APSTOCK

A different arm of the same study showed on June 5 that hydroxychloroquine, widely touted as a potential Covid treatment, had no benefit in hospitalized patients. Yesterday, based in part on those results, the Food and Drug Administration revoked an Emergency Use Authorization for using hydroxychloroquine in those patients.

From the start of the pandemic in March, researchers have focused on two different stages of Covid-19, which will likely require very different interventions. Some drugs are designed to directly combat the novel coronavirus, SARS-CoV-2, that causes the disease. The first medicine shown to have a benefit, remdesivir from the biotech firm Gilead Sciences, falls into this category, even though, because it must be given intravenously, it has been tested in hospitalized patients. Remdesivir shortens the course of infection, but has not been shown to save lives.

After patients have become profoundly sick, the problem starts to become not only the virus but their own immune system, which attacks the lungs, a condition called acute respiratory distress syndrome, or ARDS. For these patients, doctors have believed, they would need to dampen patients' immune response even as they fought the virus.

Initially, excitement in this area fell on new and expensive drugs, such as Actemra, a rheumatoid arthritis drug from Roche that is used to treat a similar condition caused by some cancer immunotherapies. But a study in patients who needed oxygen showed no benefit from a similar drug, although another arm in sicker patients is continuing. The National Institutes of Health is conducting a study of an Eli Lilly pill targeting rheumatoid arthritis, an extension of the study that showed remdesivir has a benefit.

Dexamethasone, which reached the market 59 years ago, seemed an unlikely candidate to help these patients; it was seen as too crude a way of tamping down the immune system. In guidelines for physicians treating the disease, the NIH doesn't even mention the therapy. Studies that are testing other medicines may now need to incorporate the use of the drug, which could complicate analyzing the results. A spokesperson for Regeneron, which is testing Covid-19 drugs focused on both attacking the virus and dampening the immune system, said the company's studies are written so that when a new medicine becomes the standard of care, it becomes available to patients in the trial.

Some studies have shown a benefit for using dexamethasone in acute respiratory distress syndrome not related to Covid-19, although the benefit was smaller than in RECOVERY.

The result, should it hold up to further scrutiny, shows the benefit of the strategy of Horby and Martin Landray, the Oxford researchers who designed the study, leveraging the U.K. health system to start a study of multiple inexpensive potential Covid-19 therapies — including hydroxychloroquine, dexamethasone, and also some older HIV medicines. Several months into the Covid-19 pandemic, two of the most important results come from this single study. Neither of those results, however, have been scrutinized or published. (Courtesy stastnews.com)

Southern DAILY Make Today Different

Editor's Choice

A member of Lebanese army walks past the rubble at the site of a blast in Beirut's port area, Lebanon, August 7, 2020. REUTERS/Mohamed Azakir

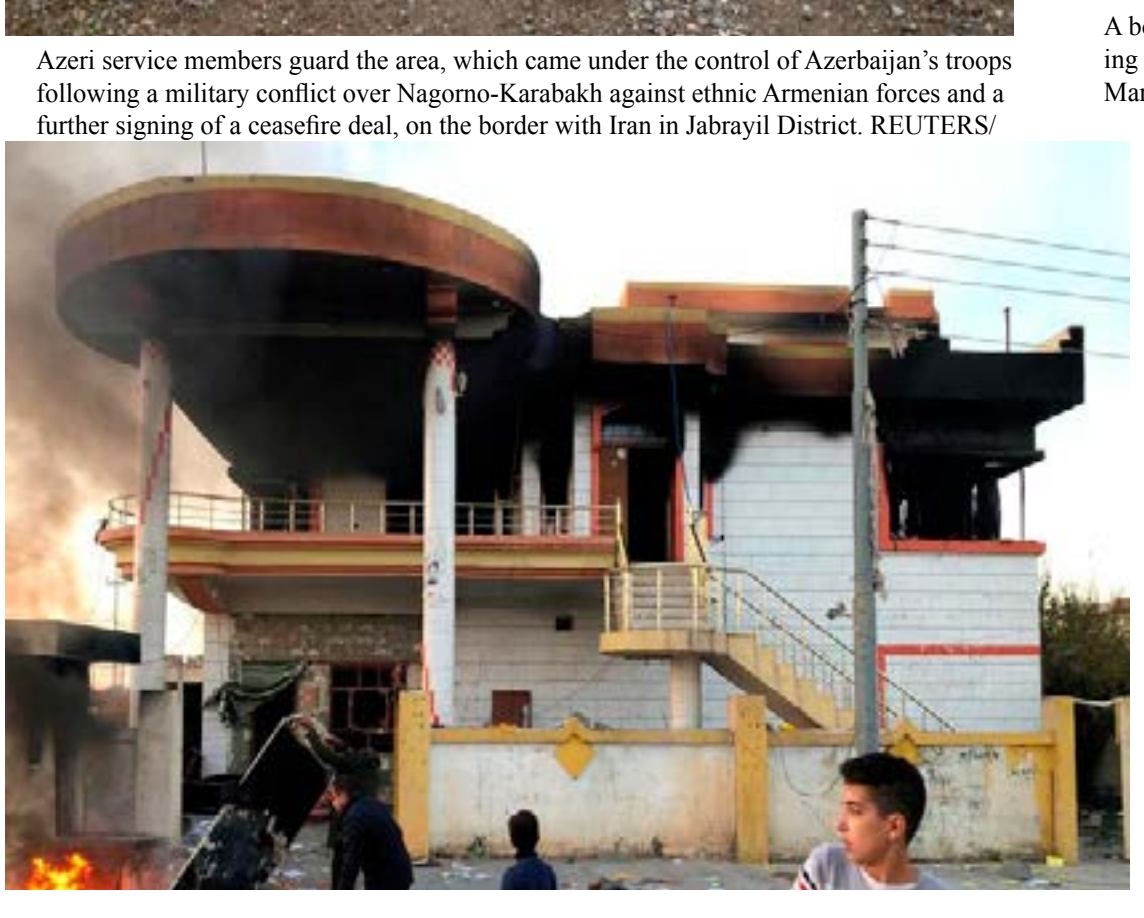
Best Supporting Actor winner Brad Pitt waits for his Oscar statue to be engraved at the Governors Ball following the 92nd Academy Awards in Los Angeles, California, February 9, 2020. REUTERS/Eric Gaillard

People dance at a park almost a year after the global outbreak of the coronavirus in Wuhan, Hubei province, China. REUTERS/Aly Song

A migrant carries her belongings following a fire at the Moria camp for refugees and migrants on the island of Lesbos, Greece, September 9, 2020. REUTERS/Elias Marcou

Azeri service members guard the area, which came under the control of Azerbaijan's troops following a military conflict over Nagorno-Karabakh against ethnic Armenian forces and a further signing of a ceasefire deal, on the border with Iran in Jabrayil District. REUTERS/

A boy gestures as a man in a Haitian National Police uniform aims a gun during a shooting in Champ de Mars, Port-au-Prince, Haiti, February 23, 2020. REUTERS/Andres Martinez Casares



The headquarters of the Kurdistan Democratic Party (PDK) is seen after it was burnt during anti-government protests on the outskirts of Sulaimaniyah, Iraq. REUTERS/Ako Rasheed

Neonatal nurse Kirsty Hartley carries newborn Theo Anderson, who was born prematurely, to his mother Kirsty Anderson, in the Neonatal Intensive Care Unit at the Lancashire Women and Newborn Centre at Burnley General Hospital, during the coronavirus outbreak, in Burnley, East Lancashire, Britain, May 15, 2020. REU-

Southern DAILY Make Today Different

COMMUNITY

More Than 300 Texas Hospitals To Receive 'Bamlanivimab,' Experimental Antibody Treatment For COVID-19

Compiled And Edited By John T. Robbins, Southern Daily Editor

The U.S. Food and Drug Administration authorized bamlanivimab for Emergency Use. Eli Lilly and Company created the drug. It is authorized for for treating mild to moderate COVID-19 in adults and pediatric patients 12 years and older with a positive COVID-19 test, who are at high risk for progressing to severe COVID-19 and/or hospitalization, according to Lilly.

Bamlanivimab should be administered as soon as possible after a positive COVID-19 test and within 10 days of symptom onset. Health care workers give it via intravenous infusion.

Clinical trials showed it could prevent a patient from going to the hospital. That indication could help our health care workers who have been battling the virus for eight months.

"I'm very proud of our people and all the healthcare workers in Houston. They've really stepped up to the challenge and continued to provide really great care, but it is wearing, and it's something we worry about as the pandemic continues to be present," said Dr. David Callendar, President and CEO of Memorial Hermann.

Governor Greg Abbott's office said hospitals in Texas should receive it as soon as next week.

DSHS will allocate this first distribution of bamlanivimab based on three criteria: new confirmed cases of COVID-19 in the community, new lab-confirmed COVID-19 admissions to hospitals, and total lab-confirmed COVID-19 patients in hospitals.

"This initial allotment of bamlanivimab will help health care professionals effectively treat cases of COVID-19 within their communities and aid in reducing hospitalizations," Gov. Abbott said. "I thank the U.S. Department of Health and Human Services for providing Texas with this crucial antibody therapy that will help keep Texans safe and mitigate the spread of COVID-19."

Texas is receiving the second-highest number of shipments of the drug, behind Illinois, according to DSHS.

Hospitals in the Houston and Galveston/Beaumont trauma service areas will receive more than 700 doses. Each patient receives one dose, according to DSHS.

A spokesperson said they expect weekly shipments from the federal government.

Chris Costa
@ChrisCostaTV
Nov 13
@TexasDSHS
tells me they've allocated it to 300+ hospitals across TX. For the first round, more than 700 doses (1 per person) will be going to #Houston and #Galveston / Beaumont trauma service areas. Expecting add'l allocations from fed govt every week
@KHOU
#khou11 #COVID19

==========

Gov. Greg Abbott
@GovAbbott
@TexasDSHS
is allocating an initial shipment of bamlanivimab, the
@LillyPad
monoclonal antibody therapy, to be distributed as early as next week to acute care hospitals across the state to help effectively treat #COVID19 & aid in reducing hospitalizations.

These weekly shipments of doses have been provided to the state at no cost through the U.S. Department of Health and Human Services.

"It's going to be a big benefit to us," said Chris Van Deusen, Director of Media Relations for Texas DSHS. "Every time we see a new medication, something that looks promising, it's a step in the right direction, and we're one step closer to finally getting through this issue."

Lilly anticipates manufacturing up to 1 million doses of bamlanivimab 700 mg by the end of 2020, for use around the world through early next year.

• Bamlanivimab is **NOT** authorized for use in patients:

o who are hospitalized due to COVID-19, OR

o who require oxygen therapy due to COVID-19, OR

o who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related co-morbidity.

Doctors are urging people to be extra diligent with masking and social distancing, even around close friends and family, to prevent a second surge. Dr. Callendar said roughly 50 percent of people who test positive for COVID-19 show no signs of being sick.

"I think we still have time to control this one – keep it from becoming what we saw in the middle of the summer," Dr. Callendar said.

His message comes as Texas' rates of COVID-19 soar back to more than 10,000 cases a day for three straight days. The last time Texas saw those levels was in mid-July, the worst of the pandemic.

"It's still going to take everybody taking those everyday steps to really put a dent in that big increase in cases we've seen recently," Van Deusen said.

Related

Arthritis drug 'cuts elderly Covid-19 deaths by two-thirds', say researchers - raising hopes that it will save the most vulnerable

KEY POINTS

Daily drug reduces deaths by 71 per cent in those with moderate or severe illness

Drug baricitinib, marketed as Olumiant, has only been available for three years

Medics hope the arthritis drug could help save most vulnerable to coronavirus

An arthritis drug has been found to cut deaths in patients admitted to hospital with COVID-19 by a remarkable two-thirds – giving medics a powerful new weapon in their armoury against the disease.

The daily pill, first earmarked as a potential Covid game-changer by a British firm, reduces deaths by 71 per cent in those with moderate or severe illness, researchers say.

Importantly, it works in the elderly, raising hopes that it will save the most vulnerable.

Called baricitinib, and marketed under the brand name Olumiant, it is a relatively new drug for rheumatoid arthritis that has been available for only three years.

An arthritis drug has been found to cut deaths in patients admitted to hospital with Covid-19 by a remarkable two-thirds. Picture: Stock

But in February it was identified as a strong candidate to help treat what was then the new threat of Covid-19. The drug was picked out by London-based BenevolentAI, which examined thousands of existing medicines for signs they might combat Covid.

Its artificial intelligence program predicted baricitinib would 'reduce the ability of the virus to infect lung cells'.

Now the idea has been validated with pan-European researchers, led by Sweden's Karolinska Institute, reporting baricitinib slashes death rates in those admitted to hospital with the disease by two-thirds. (Courtesy www.dailymail.co.uk/)

婚姻觀 Daily News

关于婚姻你需要知道点新鲜的

婚姻是一门学问，仅有激情是不够的，貌似稳定的关系仍会面对很多大大小小的矛盾冲突，甚至可能最终分道扬镳。

要想与另一半建立起持久、稳固的恋情，你需要掌握一定的技巧，尤其要注意，不要让以下的这些因素毁了你们好不容易建立起的关系。

婚姻法不保护感情，法律没有规定一个人必须爱另一个人一辈子。

无论是新婚夫妇还是相濡以沫的老夫老妻，婚姻这门课是我们一生要学习的，因为婚姻影响着一个人及一个家。

婚姻中大多数痛苦，都来源于攀比。

常说“你为什么不能像人家老公、人家老婆一样呢？”

挂在口边，抱怨丈夫赚得少，抱怨妻子脾气不好，却常常忽略了自己妻子或者丈夫的优点。

一个人的心不是靠抢夺和抓住就能留下，而是一颗心走向另一颗心。

好的夫妻关系，没有期待，各自强大，这样才能创造精彩。

婚姻是什么？没有步入婚姻的人，很难真正理解这种没有血亲却又千丝万缕的联系。

它神圣，而庄重。

你是我交过命的人，请一定要好好珍惜，这一世的夫妻情分。

因为每一段婚姻走到最后，都是生命对生命的托付。

婚姻是为了更深的东西：

为了亲密，为了一种相互归属，为了要去做一个人无法单独做的事，为了要去做两个人可以一起做的事，为了要去做一种需要两个人在一起、深深地在一起才能够做的事。

生命的本质就是爱，而婚姻是给爱，找一个家。

心若没有栖息的地方，到哪都是流浪。

我们经常不被允许做真实的自己，被许多约定俗成的信念所制约，当一个生命想要跳出制约。

活出真实的自己时，往往会被抗拒和拒绝。

如果一开始的感受是被束缚的，我相信许多人不会走入婚姻。

我们终其一生，需要的是一个愿意注视着我们的人，一个愿意敞开心扉被我们注视的人。

世界那么大，诱惑那么多，可我的目光只追随着你，与你对视。

任皱纹堆砌在脸上，任身体被时间侵蚀，在彼此欣赏和期待的目光中，任性地做着你的爱人。

这样的婚姻，难道不是我们终其一生追求的吗？

而婚姻中的那个人，是我们想要如实表达真实自己的那个人，现实却往往不随人愿。

当走进婚姻的那一刻，双方不再真实，不再袒露自己的心扉。

许多人的婚姻就算两个人在一起，也是很冷清的。

厨房里的萧条，客厅里的沉默，还有卧室里的相看两厌。

多少人，都是在婚姻失败后，才意识到，自己当年是毫无准备就走进了婚姻。

没有任何一段婚姻是可以躺在过去偷懒的，这就像开一家店，再好的地段，也是需要好好经营的。

萧伯纳说：反正结婚，不结婚你们都会后悔的。

你在山洞里清净打坐十年，带给你的心灵成长，都不及你和自己的伴侣相处一个月。

婚姻除了生养孩子，真的是人世间最伟大的一场心灵成长游戏，你可以不去互动，你同时也失去了最快速，最深刻成长的机会。

你期待婚姻它好的一面，也得去接纳它带给你的成长之前的痛苦。

结婚其实是两个人的结合与两个家庭的相遇，你们的婚姻中不可避免的会出现婆媳关系、姑嫂关系等，这些你们会怎么面对？

婚姻再往前走一步，就会遇见孩子，遇见你们此时最珍视的那个人。

亲子关系也是对夫妻关系的考验，这些你们会怎么面对？

幸福的婚姻，是两个人彼此努力靠近的结果；

而不幸的婚姻，只需要一个人，用放大镜挑着另一个人的缺点，就已经足够了。

在彼此热爱的人眼中，变老变丑，都是浪漫的事情；

在不知满足、不会感恩的人眼中，爱人在马桶上的样子，都颠覆了女神的形象，可以成为攻击的理由。

在感情中，有太多人看似“沧桑”，心理上却是伴侣的“孩子”，他们自私、懦弱、贪婪、喜欢逃避……

而更可悲的是，他们可能意识不到自己的身上存在问题，而习惯去指责和抱怨对方。

所以，在婚姻中，每一点一滴的小细节，都能体现出我们对婚姻的责任感和对伴侣的爱，而积攒失望，只会感情破裂。

婚姻让人找到了共同生活的伴侣，人们倾向于在婚姻中寻找安全感和稳定性，随着时间的推移，只是为了满足彼此需要而存在的婚姻会慢慢失去激情。

如果夫妻可以保持自己的独立性，让对方看到自己在熟悉的领域活跃着，就可以始终保持一种新鲜的视角去看待对方。

建议：如果你想继续保留激情的火花，那么就给你的伴侣留出空间，让伴侣去做自己擅长的事情。

当伴侣展现出自信时，要趁此机会好好欣赏对方。

当然，许多人在婚姻中会面临一个情况：婚外情

心理学家试图让出轨者列举出为什么是那个人？

究竟是什么提供给了这些处于稳定婚姻中的人这么大的诱惑，不顾一切的冒险呢？

虽然出轨的理由不尽相同，这其中竟暗含着一个相似的主题。

那就是：外遇是发现自我的一种方式，是对新的（或丢失的）人格身份的寻找。

为什么处于稳定感情状态中的人也有可能出轨。

有时候我们躲避着爱人的目光，不是真的在躲避他们，而是在躲避这个陈旧的自己。

许多在外遇中收获最多的并不是外遇对象，而是一个重新焕发着光芒的自己，一个新的自己。

或者是在婚姻当中不被认可的那个自己。

很多成年女性的心里，都住着一个渴望被爱的小女孩。

“她”希望被人关注，被人重视，被人疼爱。

因为只有被爱时，“她”才能强烈地感受到自我存在的价值。

男人为了证明自己是个完整的男人，可能会作出任何事情。

这种人仍在挣扎着向别人证明自己是独立的，自己是个男人

出轨是因为觉得自己毫无价值，觉得世界上并没有人会真的爱他们。

低自尊的人总是对生活缺乏一种安全感，通过拥有关系外伴侣的形式来证明自己是具有性吸引力的，而且，他们需要持续不断地这种确认，因此可能会拥有不止一个出轨对象，或者持续处于出轨的状态中。

婚姻既是爱情的结合，也是在此基础上继而产生亲情、友情的一种特别情感。

如果光有爱情没有亲情，还能继续维持。

如果婚姻里没有爱情，只有亲情或友情，那婚姻将如一潭死水，无法得到良性循环。

相识，相知，相爱，相守，相濡以沫，相伴一生。

婚姻就像通关游戏，每一关都有挑战，也都是成长。