新型冠状病毒信息简报

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上海科技大学免疫化学研究所

生物医学大数据平台和高通量筛选平台领衔编译制作

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1. 2020 年 2 月 25 日疫情

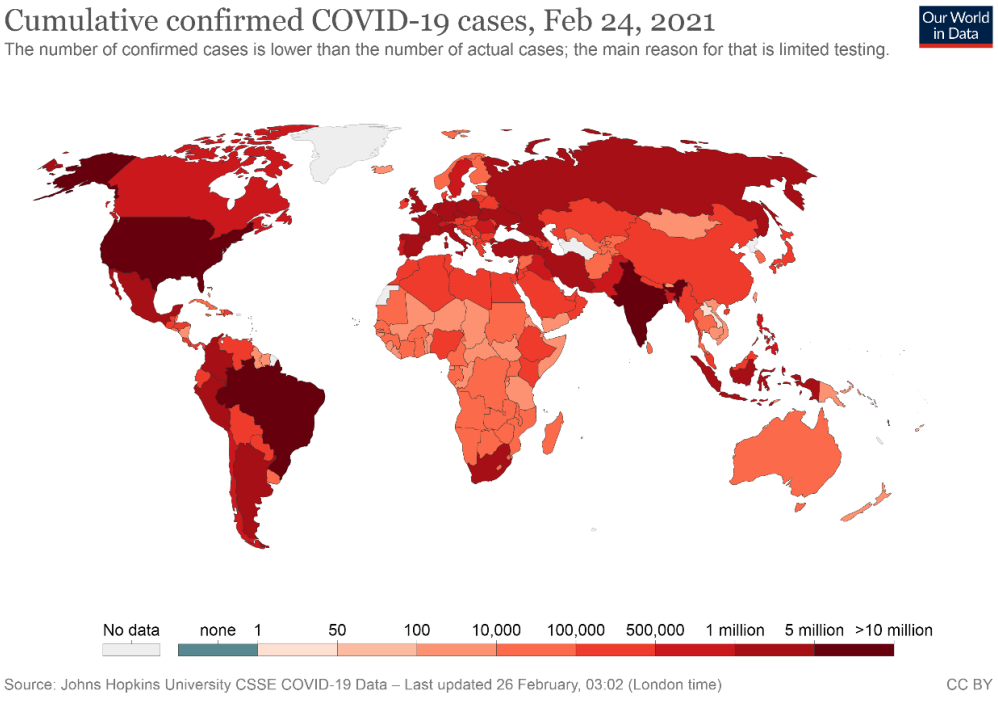
数据来源：WHO

发布时间：2021 年 2 月 25 日北京时间下午 4 点

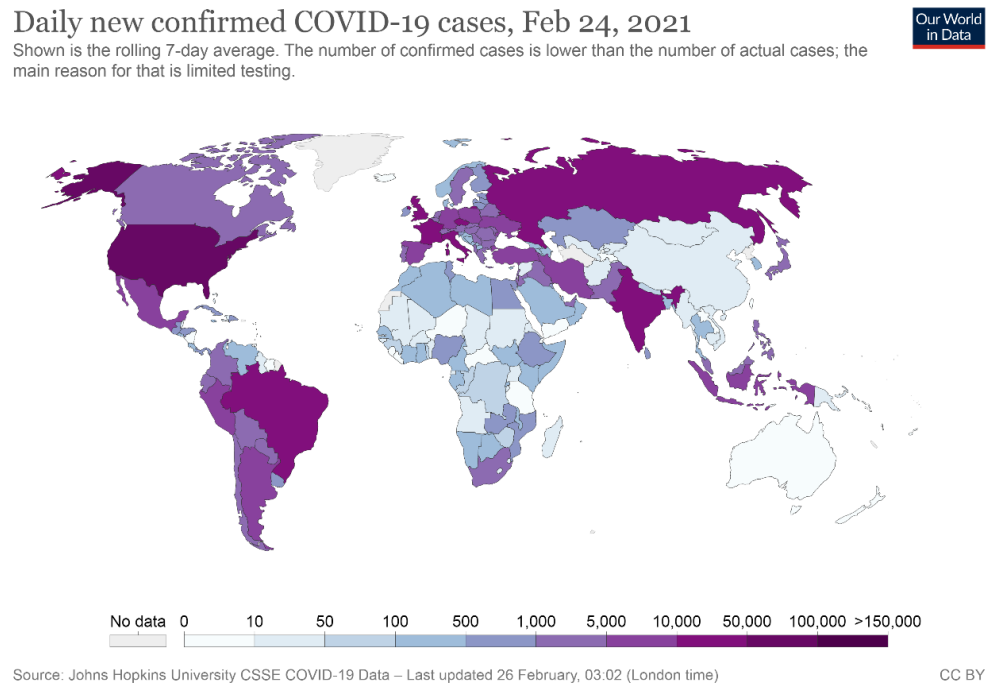
链接：https://covid19.who.int/

根据 WHO 提供的数据，2021 年 2 月 25 日全球累计确诊新型冠状病毒病人 **112,209,815** 例，当日新增确诊 **421,407** 例，累计死亡 **2,490,776** 例，当日新增死亡 **10,508**。

中国累计确诊 101,778 例，累计死亡 4,843 例，当日新增确诊 28 例，新增死亡 1 例。



世界各国确诊人数分布图（https://ourworldindata.org/covid-cases?country=~OWID_WRL#what-is-the-daily-number-of-confirmed-cases）



世界各国每日新增确诊人数分布图（https://ourworldindata.org/covid-cases?country=~OWID_WRL#what-is-the-daily-number-of-confirmed-cases）

全国新型冠状病毒肺炎新增确诊病例分布图（2 月 25 日，来源：http://2019ncov.chinacdc.cn/2019-nCoV/）

2. 一项预印本研究表明 2020 年 10 月份肯尼亚的卡车司机和助手群体针对 SARS-COV-2 的 IgG 的血清学检测阳性率为 42.3%

Seroprevalence of anti-SARS-CoV-2 IgG antibodies among truck drivers and assistants in Kenya

来源：medrxiv

发布时间：2021-02-17

链接：https://www.medrxiv.org/content/10.1101/2021.02.12.21251294v1

3. 高通量临床检测 SARS-CoV-2 中和抗体滴度方法的开发和验证

Development and Validation of a High-Throughput Clinical Assay for Measuring SARS-CoV-2-Neutralizing Antibody Titers

来源：medrxiv

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链接：https://www.medrxiv.org/content/10.1101/2021.02.16.21251653v1

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中文摘要：

中和抗体的产生是预防未来感染的关键决定因素，但是目前尚未开发出得到充分验证的高通量测定 SARS-CoV-2 中和抗体滴度的方法。文中研究者建立了一种名为 IMMUNO-COV™ v2.0 的

基于水疱性口炎病毒载体（VSV）的复制型重组新冠病毒 VSV-SARS2-Fluc 对新冠病毒中和抗体的检测方法。该检测通过携带荧光素酶报告基因的水泡性口炎病毒对阻断感染 Vero-ACE2 细胞的抗体进行滴定。研究结果显示使用由 SARS-CoV-2 S 蛋白单克隆抗体浓度梯度标准曲线计算的抗体滴度与使用 SARS-CoV-2 临床分离病毒株进行的金标准 PRNT50 试验（噬菌斑中和实验）获得的滴度密切相关($p<0.0001$)。IMMUNO-COV™v2.0 检测方法在 242 次分析运行中获得的数据进行了全面验证，数据样本包括两个单独的病毒批次和 176 个血液样本。基于对包括线性，动态范围，空白限和检测低限，稀释线性和平行度，精密度，临床一致性，基质效应,临床特异性和灵敏度等参数的评价,此方法测定性能在临床上可用于人血清和血浆。目前已储备了足够的 VSV-SARS2-Fluc 病毒试剂来检测 500 万临床样品。此外使用 IMMUNO-COV™ v2.0 方法对 SARS-CoV-2 康复人群抗体滴度测定结果显示，在康复后 6 个月期间抗体滴度显著下降。这些研究结果表明 IMMUNO-COV v 2.0 在接种疫苗的个体和从自然感染中恢复的个体中测量 SARS-CoV-2 中和抗体的可行性和实用性。此类监测可用于更好地了解需要何种水平的中和抗体来预防 SARS-CoV-2，以及需要何种强化给药方案来维持疫苗诱导的免疫。

Abstract

Neutralizing antibodies are key determinants of protection from future infection, yet well-validated high-throughput assays for measuring titers of SARS-CoV-2-neutralizing antibodies are not generally available. Here we describe the development and validation of IMMUNO-COV™ v2.0 a scalable surrogate virus assay, which titrates antibodies that block infection of Vero-ACE2 cells by a luciferase-encoding vesicular stomatitis virus displaying SARS-CoV-2 spike glycoproteins (VSV-SARS2-Fluc). Antibody titers, calculated using a standard curve consisting of stepped concentrations of SARS-CoV-2 spike monoclonal antibody, correlated closely ($p<0.0001$) with titers obtained from a gold-standard PRNT50% assay performed using a clinical isolate of SARS-CoV-2. IMMUNO-COV™ v2.0 was comprehensively validated using data acquired from 242 assay runs performed over seven days by five analysts, utilizing two separate virus lots, and 176 blood samples. Assay performance was acceptable for clinical use in human serum and plasma based on parameters including linearity, dynamic range, limit of blank and limit of detection, dilutional linearity and parallelism, precision, clinical agreement, matrix equivalence, clinical specificity and sensitivity, and robustness. Sufficient VSV-SARS2-Fluc virus reagent has been banked to test 5 million clinical samples. Notably, a significant drop in IMMUNO-COV™ v2.0 neutralizing antibody titers was observed over a six-month period in people recovered from SARS-CoV-2 infection. Together, our results demonstrate the feasibility and utility of IMMUNO-COV™ v2.0 for measuring SARS-CoV-2-neutralizing antibodies in vaccinated individuals and those recovering from natural infections. Such monitoring can be used to better understand what levels of neutralizing antibodies are required for protection from SARS-CoV-2, and what booster dosing schedules are needed to sustain vaccine-induced immunity.

4. 密集采样的病毒轨迹表明，与非 B.1.1.7 SARS-CoV-2 相比，B.1.1.7 变种急性感染的持续时间更长

Densely sampled viral trajectories suggest longer duration of acute infection

with B.1.1.7 variant relative to non-B.1.1.7 SARS-CoV-2
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中文摘要：
为了测试 B.1.1.7 的急性感染是否与更高或更高的持续鼻咽病毒浓度相关联，我们评估了在 65 名感染 SARS-CoV-2 的个体中进行的纵向 PCR 测试，这些个体正在接受日常监测测试，其中包括 7 例感染 B.1.1.7。对于感染了 B.1.1.7 的个体，增殖阶段的平均持续时间为 5.3 天（90%可信区间[2.7，7.8]），清除阶段的平均持续时间为 8.0 天[6.1，9.9]，而 平均总感染持续时间（增殖加清除）为 13.3 天[10.1，16.5]。与之相比，非 B.1.1.7 病毒的平均增殖期为 2.0 天[0.7,3.3]，平均清除期为 6.2 天[5.1,7.1]，平均感染持续时间为 8.2 天[6.5,9.7]。B.1.1.7 的病毒峰值浓度为 19.0 Ct [15.8，22.0]，而非 B.1.1.7 的病毒峰值浓度为 20.2 Ct [19.0，21.4]。对于 B.1.1.7，这转换为 8.5 log10 RNA 拷贝/ ml [7.6，9.4]，对于非 B.1.1.7，则转换为 8.2 log10 RNA 拷贝/ ml [7.8，8.5]。这些数据提供了证据，**与非 B.1.1.7 SARS-CoV-2 相比，SARS-CoV-2 变异 B.1.1.7 可能会导致更长的感染，且具有相似的峰值病毒浓度**。延长的持续时间可能有助于 B.1.1.7 SARS-CoV-2 的可传染性提高。
Abstract:
To test whether acute infection with B.1.1.7 is associated with higher or more sustained nasopharyngeal viral concentrations, we assessed longitudinal PCR tests performed in a cohort of 65 individuals infected with SARS-CoV-2 undergoing daily surveillance testing, including seven infected with B.1.1.7. For individuals infected with B.1.1.7, the mean duration of the proliferation phase was 5.3 days (90% credible interval [2.7, 7.8]), the mean duration of the clearance phase was 8.0 days [6.1, 9.9], and the mean overall duration of infection (proliferation plus clearance) was 13.3 days [10.1, 16.5]. These compare to a mean proliferation phase of 2.0 days [0.7, 3.3], a mean clearance phase of 6.2 days [5.1, 7.1], and a mean duration of infection of 8.2 days [6.5, 9.7] for non-B.1.1.7 virus. The peak viral concentration for B.1.1.7 was 19.0 Ct [15.8, 22.0] compared to 20.2 Ct [19.0, 21.4] for non-B.1.1.7. This converts to 8.5 log10 RNA copies/ml [7.6, 9.4] for B.1.1.7 and 8.2 log10 RNA copies/ml [7.8, 8.5] for non-B.1.1.7. These data offer evidence that SARS-CoV-2 variant B.1.1.7 may cause longer infections with similar peak viral concentration compared to non-B.1.1.7 SARS-CoV-2. This extended duration may contribute to B.1.1.7 SARS-CoV-2's increased transmissibility.

5. 康复者和疫苗注射者的血清对 SARS-CoV-2 B.1.1.7 变异的中和作用降低

Reduced neutralization of SARS-CoV-2 B.1.1.7 variant by convalescent and

vaccine sera
来源：cell
发布时间：2021-02-18
链接：https://www.cell.com/cell/fulltext/S0092-8674(21)00222-1
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DOI 或 PUBMED ID：https://doi.org/10.1016/j.cell.2021.02.033
编译者：刘焕珍
中文摘要：
在短短一年多的时间里，SARS-CoV-2 已造成 200 万以上的死亡，正在大规模部署疫苗。大流行的规模和容易出错的病毒复制正导致变异病毒的出现，并有可能逃避抗体反应。变种 B.1.1.7 现在在英国占主导地位，在刺突蛋白中含有 9 个氨基酸变化，包括 ACE2 相互作用表面的 N501Y。我们检测了 B.1.1.7 逃避自然 SARS-CoV-2 感染或疫苗接种引起的抗体反应的能力。我们通过对一大组具有良好特性的单克隆抗体的结构/功能分析来确定 N501Y 的影响。B.1.1.7 比亲本病毒更难被中和，通过与 501 残基的轻链接触，损害了一大类公共抗体的某些成员的中和作用。然而，没有观察到针对单克隆抗体或自然感染或疫苗接种产生的抗体反应的广泛逃逸。
Abstract:
SARS-CoV-2 has caused over 2M deaths in little over a year. Vaccines are being deployed at scale, aiming to generate responses against the virus spike. The scale of the pandemic and error-prone virus replication is leading to the appearance of mutant viruses and potentially escape from antibody responses. Variant B.1.1.7, now dominant in the UK, with increased transmission, harbours 9 amino-acid changes in the spike, including N501Y in the ACE2 interacting-surface. We examine the ability of B.1.1.7 to evade antibody responses elicited by natural SARS-CoV-2 infection or vaccination. We map the impact of N501Y by structure/function analysis of a large panel of well-characterised monoclonal antibodies. B.1.1.7 is harder to neutralize than parental virus, compromising neutralization by some members of a major class of public antibodies through light chain contacts with residue 501. However, widespread escape from monoclonal antibodies or antibody responses generated by natural infection or vaccination was not observed.

6. 展现预防无症状感染潜力，FDA 公布强生单剂新冠疫苗最新结果

来源:药明康德公众号
链接：https://mp.weixin.qq.com/s/Cat6icQ_44AJT6FmX-7IMA
摘要：2 月 26 日，美国 FDA 将召开疫苗与相关生物制品咨询委员会（Vaccines and Related Biological Products Advisory Committee,VRBPAC)会议,对强生公司(Johnson & Johnson）旗下杨森（Janssen）开发的候选新冠疫苗 Ad26.COV2.S 进行审评。今天，FDA 在官网上公布了内部科学家对 Ad26.COV2.S 的紧急使用授权（EUA）申请的评估，以及强生公司提供的最新数据。
FDA 的审评人员表示，Ad26.COV2.S 表现出良好的保护效力和安全性。值得一提的是，强生

公司提供的最新数据显示，**在南非进行的临床试验中，Ad26.COV2.S 预防出现症状的 COVID-19 的效力达到 64%，与 1 月底公布的 57%相比有所提高。而且，对无症状感染者的初步研究显示，这款疫苗可能将新冠病毒感染风险降低 65.5%**，意味着它不但可以预防 COVID-19 的发生，而且可能减少新冠病毒的传播。

7. 以色列全国大规模接种的 BNT162b2 mRNA 新冠疫苗的研究

BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting

来源：The new engl and journal of medicine

发布时间：2021-2-24

链接：https://www.nejm.org/doi/full/10.1056/NEJMoa2101765?query=featured_home

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中文摘要：

背景：随着全球针对 2019 年冠状病毒疾病的大规模疫苗接种运动（Covid-19）的开展，需要在不受控制的情况下针对不同人群的一系列结果评估疫苗的有效性。 在这项研究中，以色列最大的卫生保健组织提供的数据用于评估 BNT162b2 mRNA 疫苗的有效性。

方法：在 2020 年 12 月 20 日至 2021 年 2 月 1 日期间新接种疫苗的所有患者，根据人口统计学和临床特征，以 1：1 的比例与未接种对照进行匹配。 研究结果包括已记录的严重急性呼吸系统综合症冠状病毒 2（SARS-CoV-2）感染，有症状的 Covid-19，Covid-19 相关住院，严重疾病和死亡。 我们使用 Kaplan-Meier 估计量将每种结果的疫苗效力估计为风险率减去 1。

结果：每个研究组包括 596,618 人。第一次接种后第 14 天到第 20 天以及第二次接种后第 7 天或更多天的估计研究结果疫苗效力如下：对于已记录的感染，46%（95%置信区间[CI]为 40 至 51）和 92%（95%CI，88 至 95）；有症状的 Covid-19，57%（95%CI，50 至 63）和 94%（95%CI，87 至 98）；住院率分别为 74%（95%CI，56 至 86）和 87%（95%CI，55 至 100）；对于严重疾病，分别为 62%（95%CI，39 至 80）和 92%（95%CI，75 至 100）。首次给药后第 14 天到 20 天，估计预防 Covid-19 死亡的有效性为 72%（95%CI，19 至 100）。在针对不同年龄段的已记录的感染和有症状的 Covid-19 评估的特定亚人群中，估计的有效性是一致的，在多种并存疾病患者人群中的有效性可能略低。

结论：这项在全国范围内进行大规模疫苗接种的研究表明，BNT162b2 mRNA 疫苗对于与 Covid-19 相关的多种结局都有效，这一发现与随机试验的结果一致。

Abstract:

BACKGROUND

As mass vaccination campaigns against coronavirus disease 2019 (Covid-19) commence worldwide, vaccine effectiveness needs to be assessed for a range of outcomes across diverse populations in a noncontrolled setting. In this study, data from Israel’s largest health care organization were used to evaluate the effectiveness of the BNT162b2 mRNA vaccine.

METHODS

All persons who were newly vaccinated during the period from December 20, 2020,

to February 1, 2021, were matched to unvaccinated controls in a 1:1 ratio according to demographic and clinical characteristics. Study outcomes included documented infection with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), symptomatic Covid-19, Covid-19–related hospitalization, severe illness, and death. We estimated vaccine effectiveness for each outcome as one minus the risk ratio, using the Kaplan–Meier estimator.

RESULTS

Each study group included 596,618 persons. Estimated vaccine effectiveness for the study outcomes at days 14 through 20 after the first dose and at 7 or more days after the second dose was as follows: for documented infection, 46% (95% confidence interval [CI], 40 to 51) and 92% (95% CI, 88 to 95); for symptomatic Covid-19, 57% (95% CI, 50 to 63) and 94% (95% CI, 87 to 98); for hospitalization, 74% (95% CI, 56 to 86) and 87% (95% CI, 55 to 100); and for severe disease, 62% (95% CI, 39 to 80) and 92% (95% CI, 75 to 100), respectively. Estimated effectiveness in preventing death from Covid-19 was 72% (95% CI, 19 to 100) for days 14 through 20 after the first dose. Estimated effectiveness in specific subpopulations assessed for documented infection and symptomatic Covid-19 was consistent across age groups, with potentially slightly lower effectiveness in persons with multiple coexisting conditions.

CONCLUSIONS

This study in a nationwide mass vaccination setting suggests that the BNT162b2 mRNA vaccine is effective for a wide range of Covid-19–related outcomes, a finding consistent with that of the randomized trial.

8. 牛津大学新冠疫苗 AZD1222 首免至二免间隔时间对疫苗免疫原性和免疫效率的影响:四组随机临床试验的数据分析：二免间隔时间延长到 2 个月效果更好

Single-dose administration and the influence of the timing of the booster dose on immunogenicity and efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine: a pooled analysis of four randomised trials

来源：The LANCET

发布时间：2021-2-19

链接：

https://www.sciencedirect.com/science/article/pii/S0140673621004323?via%3Dihub

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中文摘要：

背景：Chadox1 ncov-19 疫苗(AZD1222)是牛津大学研制以黑猩猩腺病毒为载体插入 Spike 全蛋白的新冠病毒疫苗。AZD1222 疫苗已被英国政府批准用于紧急接种，间隔 4-12 周两次免疫标准剂量疫苗，并计划即刻对英国高危人群进行首次疫苗接种，并于 12 周后接种第二剂疫苗。本研究对 AZD1222 临床试验进行深入预定性分析并对首免和二免期间免疫原性和

免疫持续性影响因素进行探索性分析。同时也报道了该疫苗首免后的免疫原性和保护性。
方法：本研究数据来源于三项单盲随机临床试验和一项南非双盲Ⅰ/Ⅱ期临床(cov005)。18岁以上的受试者按1:1随机分配后免疫两针azd1222（5×10¹⁰个病毒粒子）或对照疫苗或安慰剂。英国临床试验中，部分受试者首次免疫了低剂量的疫苗 (2.2×10¹⁰个病毒粒子)。初级判定结果是二免14天后进行核酸检测结合临床症状(发烧超过37.8oC，咳嗽，呼吸困难，嗅觉丧失或老年痴呆)。二级疗效分析包括首免22天后感染病例。免疫效价和假病毒中和法滴度检测抗体效价以衡量免疫效果。DNA检测阳性样品均由权威机会进行认定。初步分析中受试者均为新冠病毒N蛋白血清检测阴性，二免后至少随访14天，且未在检测中感染病毒。安全性评估是所有免疫过该新冠疫苗的受试人群。
结果：去年4月至12月，四项临床试验共招募24422名受试者，初步分析包括17178受试者（8597人接种AZD1222，8581人接种对照疫苗））。332例受试者在二免14天后确认新冠感染，疫苗保护效率为66.7% (95% CI：574-740)，疫苗组84例(10%) ，对照组248例(29%)。21天排除期后疫苗组的新冠感染者无住院病例，而对照组有15例住院病例。12282名疫苗组受试者有108名(0.9%)发生严重不良反应,11962名对照组收拾者中有127名(1.1%)发生严重不良反应。其中有7例死亡病例被认定与接种疫苗无关(2例为疫苗组，5例为对照组) ，其中包括对照组1例与新冠相关的死亡病例。深入研究表明单针疫苗免疫后22-90天内疫苗免疫效率为76.0% (59.3一85.9)。模型分析表明初次免疫后3个月内免疫保护力没有降低。且在此期间抗体水平维持较高水平。接受两次免疫接种的受试者中，二免间隔期长于12周的受试者的保护效率（81.3%）高于间隔期短于6周的受试者（55.1%）。且该现象也与相应抗体检测效价一致，即免疫间隔期长于12周的受试者抗体效价是免疫间隔期短于6周的受试者2倍多。
解释：这两种剂量的ChAdOx1nCoV-19的初步分析结果与试验中期分析中看到的结果一致，并证实疫苗是有效的，在探索性分析中，**结果随剂量间隔而变化。3个月的剂量间隔可能比推广大流行疫苗的剂量间隔较短的方案更有好处**，以便在供应短缺时尽早保护人口中人数最多的人，同时在接受第二次剂量后也能改善保护。
Abstract:
Background: The ChAdOx1 nCoV-19 vaccine (AZD1222) is a chimpanzee adenoviral vectored vaccine with full length SARS-CoV-2 spike insert, developed at the University of Oxford (Oxford, UK). AZD1222 vaccine has been approved for emergency use by the UK regulatory authority with their first dose immediately, and delivering the second dose 12 weeks later. Here, we provide both a further prespecified pooled analysis of trials of AZD1222 and exploratory analyses of the impact on immunogenicity and efficacy of extending the interval between priming and booster doses. In addition, we show the immunogenicity and protection afforded by the first dose, before a booster dose has been offered.
Methods: We present data from three single-blind randomised controlled trials and one double-blind phase 1/2 study in South Africa (. Individuals 18 years and older were randomly assigned 1:1 to receive two standard doses of AZD1222 (5×10¹⁰ viral particles) or a control vaccine or saline placebo. In the UK trial, a subset of participants received a lower dose (2•2×10¹⁰ viral particles) of the AZD1222 for the first dose. The primary outcome was virologically confirmed symptomatic COVID-19 disease, defined as a nucleic acid amplification test (NAAT)-positive swab combined with at least one qualifying symptom more than 14 days after the second dose. Secondary efficacy analyses included cases occuring

at least 22 days after the first dose. Antibody responses measured by immunoassay and by pseudovirus neutralisation were exploratory outcomes. All cases of COVID-19 were adjudicated for inclusion in the analysis by a independent committee. Safety was assessed in all participants who received at least one dose.

Findings: 24422 participants were recruited and vaccinated across the four studies, of whom 17178 were included in the primary analysis (8597 receiving AZD1222 and 8581 receiving control vaccine). 332 NAAT-positive infections met the primary endpoint of symptomatic infection more than 14 days after the second dose. Overall vaccine efficacy more than 14 days after the second dose was 66·7% (95% CI 57·4–74·0), with 84 (1·0%) cases in the AZD1222 group and 248 (2·9%) in the control group. There were no hospital admissions for COVID-19 in the ChAdOx1 nCoV-19 group after the initial 21-day exclusion period, and 15 in the control group. 108 (0·9%) of 12282 participants in the ChAdOx1 nCoV-19 group and 127 (1·1%) of 11962 participants in the control group had serious adverse events. There were seven deaths considered unrelated to vaccination (two in the AZD1222 group and five in the control group), including one COVID-19-related death in the control group. Exploratory analyses showed that vaccine efficacy after a single standard dose of vaccine from day 22 to day 90 after vaccination was 76·0% (59·3–85·9). Our modelling analysis indicated that protection did not wane during this initial 3-month period. Similarly, antibody levels were maintained during this period with minimal waning. In the participants who received two standard doses, after the second dose, vaccine efficacy was higher in those with a longer prime-boost interval (e 81·3% at ⩾12 weeks) than in those with a short interval (55·1% at <6 weeks). These observations are supported by immunogenicity data that showed binding antibody responses more than two-fold higher after an interval of 12 or more weeks compared with an interval of less than 6 weeks.

Interpretation: The results of this primary analysis of two doses of ChAdOx1 nCoV-19 were consistent with those seen in the interim analysis of the trials and confirm that the vaccine is efficacious, with results varying by dose interval in exploratory analyses. A 3-month dose interval might have advantages over a programme with a short dose interval for roll-out of a pandemic vaccine to protect the largest number of individuals in the population as early as possible when supplies are scarce, while also improving protection after receiving a second dose.

9. 重磅！康希诺生物新冠病毒疫苗有条件上市申请获受理

来源：药物简讯

发布时间：2021-02-24

链接：https://mp.weixin.qq.com/s/SwCOVkdH5MqoulgacVNcNg

编译者：张怡

中文摘要：

康希诺生物与军事科学院军事医学研究所生物工程研究所共同开发的重组新型冠状病毒疫苗（5 型腺病毒载体）（“ Ad5-nCoV”，商品称为克威莎™），III期临床试验期中分析数据结

果显示：在单针接种疫苗 28 天后，疫苗对所有症状的总体保护效力为 65.28%；在单针接种疫苗 14 天后，疫苗对所有症状总体保护效力为 68.83%。疫苗对重症的保护功效分别为：单针接种疫苗 28 天后为 90.07%；单针接种疫苗 14 天后为 95.47%。2021 年 2 月 21 日，本公司已正式向国家药监局提交附条件上市申请，并获得补充。2 月 24 日午间，康希诺生物宣布旗下腺病毒载体新冠疫苗的附条件上市获得受理。

10. 国药中生武汉所：新冠疫苗保护率 72.51%，上市申请获受理

来源：澎湃新闻

发布时间：2021.02.24

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编译者：张怡

中文摘要：

2 月 24 日下午，国药集团中国生物武汉生物制品研究所官网发布消息称，中国生物武汉所新冠灭活疫苗接种后安全性良好，两针免疫程序接种后，疫苗接种者均产生高滴度抗体，中和抗体阳转率为 99.06%，疫苗针对由新冠病毒感染引起的新冠肺炎的保护效力为 72.51%。2 月 21 日，中国生物武汉所已正式向国家药监局提交附条件上市申请，并获得受理。

11. 发病率下降 95.8%！首个靠疫苗遏制新冠的国家出现了？170 万人次大数据出炉

来源：生物世界

发布时间：2021-02-23

链接：https://mp.weixin.qq.com/s/SGCBfrvWRPgjhVSiOeP6lA

编译者：孔娟

据美媒 21 日报道，以色列卫生部 2 月 20 日表示，在两次注射辉瑞新冠疫苗的人群中，新冠肺炎患病率下降了 95.8%。辉瑞新冠疫苗在预防发烧或呼吸困难方面的有效率为 98%，在预防住院和死亡方面的有效率为 98.9%。截至 1 月 30 日，以色列已经有大约 170 万人接受了第二次新冠疫苗接种。研究结果表明，辉瑞疫苗对抵抗在英国发现的变异病毒有效。据悉，这一变异病毒导致的确诊病例占以色列新冠病毒确诊病例的 80%左右。另一项由以色列示巴医学中心发表在医学杂志《柳叶刀》上题为“Early rate reductions of SARS-CoV-2 infection and COVID-19 in BNT162b2 vaccine recipients”的研究表明，第一剂辉瑞疫苗的有效率为 85%，这也引发了关于是否需要注射第二剂疫苗的讨论。经过统计学 95%CI 矫正，首次接种 1-14 天内所有感染率下降 30%，15-28 天所有感染下降 75%，这是首次在一般人群中评估疫苗的有效性。因此疫苗对预防有症状感染的效果更为显著。目前，世界各国均在全力加速疫苗接种，其中以色列的接种比例最高。以色列接种已达每 100 人 78 剂，以色列的疫苗在真实世界的研究结果给我们带来了足够的安慰，更检验了疫苗的效果。目前成为海外首个成功通过疫苗遏制疫情的国家。

12. A 型流感病毒缺陷型干扰粒子(IAV-DIPs)对 SARS-CoV-2 复制的体外抗病毒活性

Antiviral activity of influenza A virus defective interfering particles against SARS-CoV-2 replication in vitro through stimulation of innate immunity

来源：biorxiv

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DOI 或 PUBMED ID：
编译者：王玮
中文摘要：
导致 COVID-19 的 SARS-CoV-2 在 2019 年末出现，并引发了一场毁灭性的大流行。虽然第一批已获批准的疫苗已于 2020 年底投入使用，但疫苗供应仍然有限。此外，病毒的免疫逃逸突变体正在出现，目前的疫苗可能只能提供有限的保护。此外，现有的抗病毒药物和针对 COVID-19 的治疗方案仅显示出有限的疗效。甲型流感病毒（IAV）缺陷型干扰粒子（DIPs）以前不仅被提出用于流感病毒的抗病毒治疗，而且被提出可用于干扰素（IFN）敏感的呼吸道病毒感染的泛特异性治疗。为了探讨 IAV-DIPs 作为治疗 COVID-19 的抗病毒药物的适用性，该研究进行了体外共感染实验，包括产生的、细胞培养衍生的 DIPs 和对 IFN 敏感的 SARS-CoV-2。该研究表明，用 IAV-DIPs 治疗可完全消除 SARS-CoV-2 的复制。此外，这种抑制作用依赖于 janus 激酶/信号转导子和转录激活子（JAK/STAT）信号。这些结果提示 IAV 抑制 SARS-CoV-2 复制的主要原因是对先天免疫的非特异性刺激。因此，建议 IAV-DIPs 作为一种有效的抗病毒药物用于治疗 COVID-19，并有可能抑制 SARS-CoV-2 新变种的复制。

Abstract:
SARS-CoV-2 causing COVID-19 emerged in late 2019 and resulted in a devastating pandemic. Although the first approved vaccines were already administered by the end of 2020, vaccine availability is still limited. Moreover, immune escape variants of the virus are emerging against which the current vaccines may confer only limited protection. Further, existing antivirals and treatment options against COVID-19 only show limited efficacy. Influenza A virus (IAV) defective interfering particles (DIPs) were previously proposed not only for antiviral treatment of the influenza disease but also for pan-specific treatment of interferon (IFN)-sensitive respiratory virus infections. To investigate the applicability of IAV DIPs as an antiviral for the treatment of COVID-19, we conducted in vitro co-infection experiments with produced, cell culture-derived DIPs and the IFN-sensitive SARS-CoV-2. We show that treatment with IAV DIPs leads to complete abrogation of SARS-CoV-2 replication. Moreover, this inhibitory effect was dependent on janus kinase/signal transducers and activators of transcription (JAK/STAT) signaling. These results suggest an unspecific stimulation of the innate immunity by IAV DIPs as a major contributor in suppressing SARS-CoV-2 replication. Thus, we propose IAV DIPs as an effective antiviral agent for treatment of COVID-19, and potentially also for suppressing the replication of new variants of SARS-CoV-2.

13. SARS-CoV-2 在美国的变异进化：随着时间的推移，可能通过一系列超级传播者事件和突变爆发，病毒突变高度积累

SARS-CoV-2 variant evolution in the United States: High accumulation of viral

mutations over time likely through serial Founder Events and mutational bursts
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DOI 或 PUBMED ID：Preprint
编译者：宋张悦
中文摘要：
COVID-19 大流行已造成超过 229 万人死亡，仍然是国际上的严重威胁。尽管诸如保持社交距离、定期封锁和卫生协议等简单措施立即生效，但感染率只是暂时降至最低。当感染率再次激增时，病毒的新变种开始出现。我们的研究集中在美国 2020 年至 2021 年初的一组具有代表性的序列上。我们表明，各种公共卫生问题背后的驱动力，是广泛的感染和超级传播者事件。特别是，我们发现随着时间的推移，突变的积累几乎没有遗传漂变的损失，包括在 Spike 区域，这可能对疫苗和治疗来说是有影响的。这种潜伏的累积遗传变异可能变得越来越普遍，并可能导致超级变异事件，从而导致变异可以逃脱现有疫苗提供的免疫保护作用。
Abstract:
Since the first case of COVID-19 in December 2019 in Wuhan, China, SARS-CoV-2 has spread worldwide and within a year has caused 2.29 million deaths globally. With dramatically increasing infection numbers, and the arrival of new variants with increased infectivity, tracking the evolution of its genome is crucial for effectively controlling the pandemic and informing vaccine platform development. Our study explores evolution of SARS-CoV-2 in a representative cohort of sequences covering the entire genome in the United States, through all of 2020 and early 2021. Strikingly, we detected many accumulating Single Nucleotide Variations (SNVs) encoding amino acid changes in the SARS-CoV-2 genome, with a pattern indicative of RNA editing enzymes as major mutators of SARS-CoV-2 genomes. We report three major variants through October of 2020. These revealed 14 key mutations that were found in various combinations among 14 distinct predominant signatures. These signatures likely represent evolutionary lineages of SARS-CoV-2 in the U.S. and reveal clues to its evolution such as a mutational burst in the summer of 2020 likely leading to a homegrown new variant, and a trend towards higher mutational load among viral isolates, but with occasional mutation loss. The last quartile of 2020 revealed a concerning accumulation of mostly novel low frequency replacement mutations in the Spike protein, and a hypermutable glutamine residue near the putative furin cleavage site. Finally, the end of the year data revealed the presence of known variants of concern including B.1.1.7, which has acquired additional Spike mutations. Overall, our results suggest that predominant viral sequences are dynamically evolving over time, with periods of mutational bursts and unabated mutation accumulation. This high level of existing variation, even at low frequencies and especially in the Spike-encoding region

may be become problematic when superspreader events, akin to serial Founder Events in evolution, drive these rare mutations to prominence.

AUTHOR SUMMARY The pandemic of coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has caused the death of more than 2.29 million people and continues to be a severe threat internationally. Although simple measures such as social distancing, periodic lockdowns and hygiene protocols were immediately put into force, the infection rates were only temporarily minimized. When infection rates exploded again new variants of the virus began to emerge. Our study focuses on a representative set of sequences from the United States throughout 2020 and early 2021. We show that the driving force behind the variants of public health concern, is widespread infection and superspreader events. In particular, we show accumulation of mutations over time with little loss from genetic drift, including in the Spike region, which could be problematic for vaccines and therapies. This lurking accumulated genetic variation may be a superspreader event from becoming more common and lead to variants that can escape the immune protection provided by the existing vaccines.

14. 一种 SARS-CoV-2 的反式互补系统可重现无毒性的真实的病毒复制

A trans-complementation system for SARS-CoV-2 recapitulates authentic viral replication without virulence

来源：cell

发布时间：2021-02-23

链接：https://www.cell.com/cell/fulltext/S0092-8674(21)00233-6

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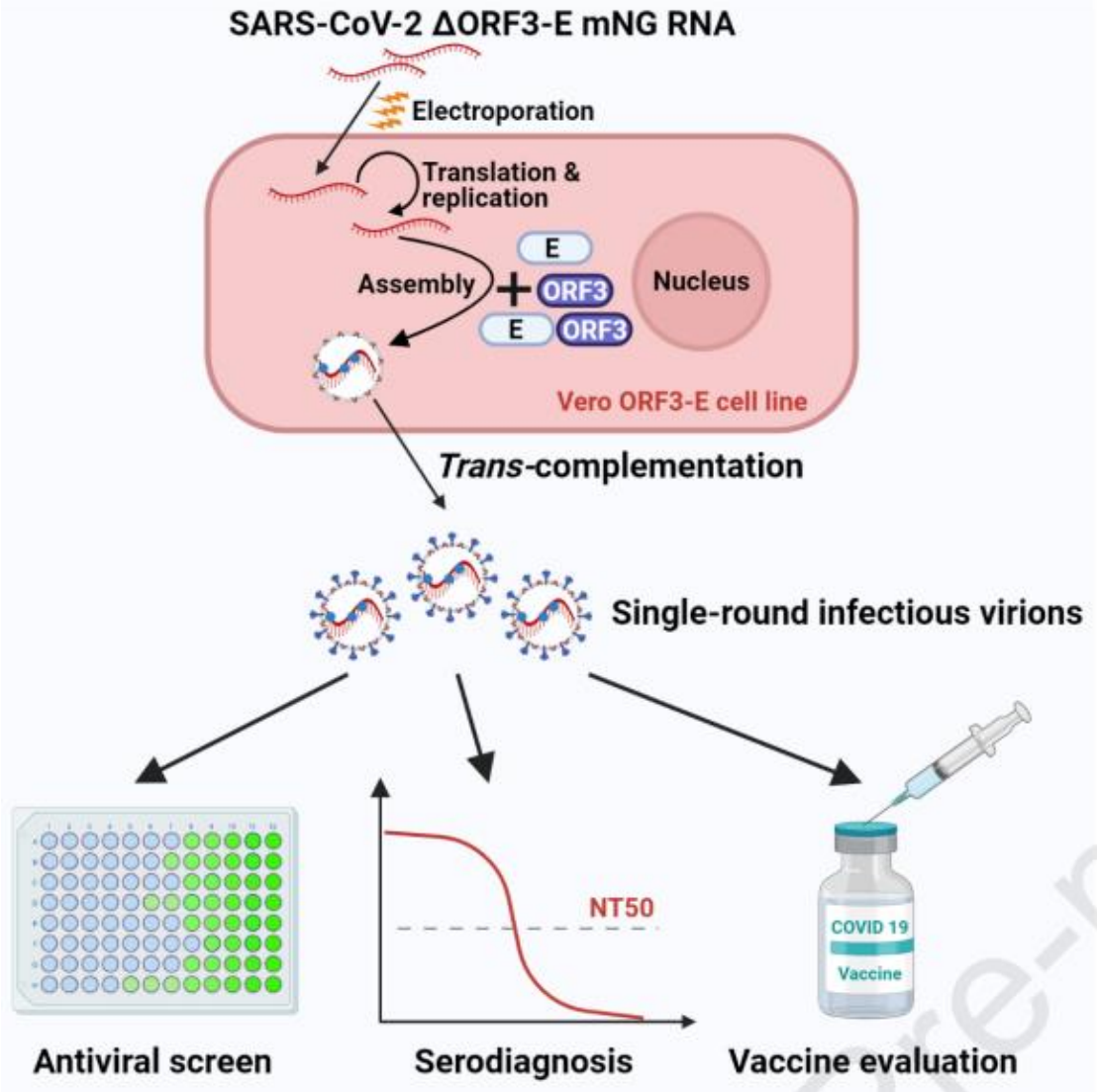
DOI 或 PUBMED ID：https://doi.org/10.1016/j.cell.2021.02.044

编译者：宋张悦

中文摘要：

培养 SARS-CoV-2 需要生物安全等级 3（BSL-3）的实验室，这是研究的一个瓶颈。本文的研究人员报告了一种反式互补系统，该系统产生单轮传染性 SARS-CoV-2，并重现了真实的病毒复制。结果证明，单轮传染性 SARS-CoV-2 可以在生物安全等级 2 级（BSL-2）实验室用于高通量中和和抗病毒测试。反式互补系统由两个部分组成：包含 ORF3 和包膜基因缺失以及突变的转录调节序列的基因组病毒 RNA，以及表达这两个缺失基因的生产细胞系。这两个成分的反式互补产生的病毒粒子只能感染一次细胞，但不会产生野生型 SARS-CoV-2。接种补体衍生病毒粒子的仓鼠和 K18-hACE2 转基因小鼠即使在颅内接种最高剂量后也未表现出可检测的疾病。因此，反式互补系统可以在 BSL-2 实验室安全地用于研究和对策开发。



Abstract:

Highlights

- A *trans*-complementation system produces single-round infectious SARS-CoV-2
- Single-round infectious SARS-CoV-2 recapitulates authentic viral infection
- Safety results support the *trans*-complementation system can be performed at BSL-2
- *Trans*-complementation assay can be used for high-throughput antiviral tests at BSL-2

Summary

The biosafety level-3 (BSL-3) requirement to culture severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a bottleneck for research. Here we report a trans-complementation system that produces single-round infectious SARS-CoV-2 that recapitulates authentic viral replication. We demonstrate that the single-round infectious SARS-CoV-2 can be used at BSL-2 laboratories for high-throughput neutralization and antiviral testing. The trans-complementation system consists of two components: a genomic viral RNA containing ORF3 and envelope gene deletions as well as mutated transcriptional regulator sequences, and a producer cell line

expressing the two deleted genes. Trans-complementation of the two components generates virions that can infect naive cells for only one round, but does not produce wild-type SARS-CoV-2. Hamsters and K18-hACE2 transgenic mice inoculated with the complementation-derived virions exhibited no detectable disease, even after intracranial inoculation with the highest possible dose. Thus, the trans-complementation platform can be safely used at BSL-2 laboratories for research and countermeasure development.

15. SARS-CoV-2 受体结合结构域的抗原性分析

The antigenic anatomy of SARS-CoV-2 receptor binding domain

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DOI 或 PUBMED ID：10.1016/j.cell.2021.02.032

编译者：宋珂

文章亮点：

• 对 377 个 mAbs 进行了筛选：在 80 个识别 RBD 的抗体中，有 19 个抗体表现出有效的中和能力，有 1 个能与 NTD 有效结合

• 解析了 19 个 Fab-antigen 复合物结构；80 个识别 RDB 的单抗中，按照抗原表位可分为 5 组

• 多数有效的 mAbs 是 ACE2 蛋白的阻断剂，能够中和少量 ACE2 蛋白，一些抗体 Fab 存在糖基化

• mAbs 表现出独特的与 NTD、RBD 结合的模式，以及 LC 优化的示例

中文摘要：

抗体是利用免疫保护抵抗 SARS-CoV-2 病毒的关键，部分抗体可以作为治疗药物在紧急情况下使用。本文中，作者鉴别出了 377 个识别病毒 spike 蛋白的人源单克隆抗体(mab)，并重点研究了其中 80 个与受体结合结构域(RBD)结合的抗体。作者设计了一套竞争数据驱动的方法来确定抗体在 RBD 上的结合位点。作者发现，尽管抗体的结合位点分布广泛，但中和性抗体的结合位点比较集中，几乎所有据备高抑制能力的单克隆抗体(IC_{50}<0.1 μg/ml)都通过阻断与受体的相互作用而起效,只有一种抗体的表位较特殊，与 N 端结构域结合。许多中和性单克隆抗体具有公共的 V 基因和相近的谱系。作者利用 X-ray 晶体学和 cryo-EM 技术解析了 19 个 Fab-antigen 复合物结构，并仔细研究了这些抗体识别抗原的结构基础。作

者发现了有抑制能力的抗体的一些全新结合模式，并在动物模型中证明了这些 mAbs 能够提供很强的中和性保护作用，可被用于预防或治疗 SARS-CoV-2 感染。

Highlights:

• Map 377 mAbs: 19 of 80 recognizing the RBD are potent neutralizers; 1 potent NTD binder

• 19 Fab-antigen complex structures; 80 mAbs mapped on RBD and clustered into 5 epitopes

• Most potent mAbs are ACE2 blockers, neutralize with few ACE2s, some Fabs glycosylated

• mAbs reveal unique examples of NTD binding, RBD binding mode and LC optimization

Abstract:

Antibodies are crucial to immune protection against SARS-CoV-2, with some in emergency use as therapeutics. Here we identify 377 human monoclonal antibodies (mAbs) recognizing the virus spike, and focus mainly on 80 that bind the receptor binding domain (RBD). We devise a competition data driven method to map RBD binding sites. We find that although antibody binding sites are widely dispersed, neutralizing antibody binding is focused, with nearly all highly inhibitory mAbs (IC50<0.1μg/ml) blocking receptor interaction, except for one that binds a unique epitope in the N-terminal domain. Many of these neutralizing mAbs use public V-genes and are close to germline. We dissect the structural basis of recognition for this large panel of antibodies through X-ray crystallography and cryo-electron microscopy of 19 Fab-antigen structures. We find novel binding modes for some potently inhibitory antibodies and demonstrate that strongly neutralizing mAbs protect, prophylactically or therapeutically, in animal models.

16. 补体激活水平升高是严重 SARS-CoV-2 感染的一个显著特征

Increased complement activation is a distinctive feature of severe SARS-CoV-2 infection

来源：bioRxiv

发布时间：2020-02-23

链接：https://www.biorxiv.org/content/10.1101/2021.02.22.432177v1

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DOI 或 PUBMED ID：

编译者：宋珂

中文摘要：

补体激活与严重 SARS-CoV-2 感染的发病机制相关。然而，人们尚不明确补体激活水平升高是否可以作为病情危重的通用指标（当然对 COVID-19 也是如此）。而且，目前还不清楚 COVID-19 病患的体内哪些通路与补体激活相关，以及补体激活是否与严重 SARS-CoV-2 感染的某些特征相关，如：内皮损伤或血凝过快。为了解决这些问题，作者对在 2 个三级护理中心预登记的 COVID-19 患者的血浆中的补体激活进行了研究。作者将这些患者的数据与其他

两组非 COVID-19 患者进行了比较：（a）组因流感而住院的患者，以及（b）组因急性呼吸衰竭而进入重症监护病房（ICU）的患者，（b）组患者需要进行有创机械人工呼吸(IMV)。作者发现，与流感和非患 COVID-19 而呼吸衰竭的患者相比，COVID-19 患者的补体激活循环标志物(如：sC5b-9)的水平会升高。而且，该现象还有助于区分那些会发展为更严重后果，如：进入 ICU 或需要 IMV，的高风险患者。此外，研究结果表明，增强的替代补体通路激活在重症 COVID-19 患者中最为普遍，并与内皮损伤标志物(如：Ang2)以及血凝过快(即血栓调节蛋白和血管性血友病因子)相关。作者的研究发现，补体激活是 COVID-19 的一个独特特征，并指出了可能用于风险预测、药物发现和个性化临床试验的特定靶点。

Abstract:
Complement activation has been implicated in the pathogenesis of severe SARS-CoV-2 infection. However, it remains to be determined whether increased complement activation is a broad indicator of critical illness (and thus, no different in COVID-19). It is also unclear which pathways are contributing to complement activation in COVID-19, and, if complement activation is associated with certain features of severe SARS-CoV-2 infection, such as endothelial injury and hypercoagulability. To address these questions, we investigated complement activation in the plasma from patients with COVID-19 prospectively enrolled at two tertiary care centers. We compared our patients to two non-COVID cohorts: (a) patients hospitalized with influenza, and (b) patients admitted to the intensive care unit (ICU) with acute respiratory failure requiring invasive mechanical ventilation (IMV). We demonstrate that circulating markers of complement activation (i.e., sC5b-9) are elevated in patients with COVID-19 compared to those with influenza and to patients with non-COVID-19 respiratory failure. Further, the results facilitate distinguishing those who are at higher risk of worse outcomes such as requiring ICU admission, or IMV. Moreover, the results indicate enhanced activation of the alternative complement pathway is most prevalent in patients with severe COVID-19 and is associated with markers of endothelial injury (i.e., Ang2) as well as hypercoagulability (i.e., thrombomodulin and von Willebrand factor). Our findings identify complement activation to be a distinctive feature of COVID-19, and provide specific targets that may be utilized for risk prognostication, drug discovery and personalized clinical trials.

17. 为什么各种 COVID 疫苗很难进行比较

Why COVID vaccines are so difficult to compare

来源：nature

发布时间：2021-02-23

链接：https://www.nature.com/articles/d41586-021-00409-0

编辑：Heidi Ledford

DOI 或 PUBMED ID：https://doi.org/10.1038/d41586-021-00409-0

编译者：刘焕珍

中文摘要：

尽管已经推广了几种疫苗，但可能尚需几个月的时间才能对其进行排名。巴西的公共卫生研究人员说，这是一个由有限的供给和有限的数据所影响的决定，目前还不可能比较这些疫苗。

鉴于在有限的供应中对速度的需求，对疫苗进行排名的任何努力都不仅要考虑其报告的有效性，而且还要考虑供应、成本、部署疫苗的物流、疫苗提供的保护的持久性以及它们抵御新出现的病毒变体的能力。研究人员也开始测试一系列剂量、时间和疫苗组合。他们仍然不知道疫苗介导的免疫能持续多长时间，也不知道各种疫苗减少冠状病毒传播的程度如何——所有这些因素都可能决定哪种疫苗被认为是“最好的”。Kim 说，最终，对于在哪种环境下使用哪种疫苗可能更具策略性。但是目前，数据还不存在。

Abstract:
Despite the widespread roll-out of several vaccines, it could be months before they can be ranked. It is a decision shaped by limited supplies and hampered by limited data, says Cristina Possas, a public-health researcher at the Oswaldo Cruz Foundation in Rio de Janeiro, Brazil. “It is not possible to compare these vaccines at this point,” she says. Given the demand for speed amid limited supplies, any effort to rank the vaccines must take into account not only their reported effectiveness, but also supplies, costs, the logistics of deploying them, the durability of the protection they offer and their ability to fend off emerging viral variants. Researchers are also starting to test a range of doses, schedules and combinations of vaccines. They still do not know how long vaccine-mediated immunity will last, or how well the various vaccines reduce coronavirus spread — all factors that could shape which is considered the ‘best’. Eventually, it might be possible to be more strategic about which vaccines to use in which settings, says Kim. But for now, the data simply aren’t there.

18. 新冠病毒疫苗能阻止病毒传播吗？科学家们竞相寻找答案

Can COVID vaccines stop transmission ? Scientists race to find answers

来源：nature
发布时间：2021.02.19
链接：https://www.nature.com/articles/d41586-021-00450-z
作者：Smriti Mallapaty
doi: https://doi.org/10.1038/d41586-021-00450-z
编译者：张怡

中文摘要：
随着各国推出预防 COVID-19 的疫苗，目前正在进行研究，以确定注射疫苗是否也能阻止人们感染和传播 SARS-CoV-2 病毒。如果给足够多的人接种，预防传播的疫苗可以帮助控制大流行。初步分析表明，至少有一些疫苗可能具有阻断传播的效果。但是，要确认这种影响——以及这种影响将有多强——是很困难的。虽然 COVID-19 疫苗的大多数临床试验表明，疫苗可以预防疾病，但一些试验结果也提供了注射可能预防感染的线索。疫苗可能不会阻止或显著降低感染的机会。但接种疫苗可能会降低感染者传播病毒的能力，或者降低他们的传染性，从而减少传播。为了真正确定疫苗是否能预防传播，研究人员正在追踪接种过疫苗的人的密切接触者，看他们是否间接地免受感染。

Abstract
As countries roll out vaccines that prevent COVID-19, studies are under way to determine whether shots can also stop people from getting infected and passing on the SARS-CoV-2 virus. Vaccines that prevent transmission could help to bring the pandemic under control if they are given to enough people. Preliminary

analyses suggest that at least some vaccines are likely to have a transmission-blocking effect. But confirming that effect — and how strong it will be — is tricky.

Although most clinical trials of COVID-19 vaccines showed that vaccines prevented the disease, some trial results also offered clues that shots might prevent infection. It's possible that vaccines won't stop or significantly lessen the chances of infection. But jabs might make infected people less able to pass the virus on, or make them less infectious, and so reduce transmission. To really nail down whether vaccines prevent transmission, researchers are tracking the close contacts of vaccinated people to see whether they are being indirectly protected from infection.

19. FDA 发布了针对 COVID-19 新突变株的关于疫苗、诊断以及治疗的一系列指南

Coronavirus (COVID-19) Update: FDA Issues Policies to Guide Medical Product Developers Addressing Virus Variants

来源：FDA

发布时间：2021-02-22

编译：王玮

链 接 ： https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-policies-guide-medical-product-developers-addressing-virus

其中，FDA 更新了针对紧急授权使用疫苗预防 COVID-19 的相关指南。

链接：https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19

发布了评估 COVID-19 病毒突变体对 COVID-19 检测影响的指南

Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests

链接：https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-evaluating-impact-viral-mutations-covid-19-tests

FDA 发布的针对开发治疗 COVID-19 的单克隆抗体产品的指南，包括怎么解决新发突变株的问题

Development of Monoclonal Antibody Products Targeting SARS-CoV-2, Including Addressing the Impact of Emerging Variants, During the COVID 19 Public Health Emergency 链接：https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-monoclonal-antibody-products-targeting-sars-cov-2-including-addressing-impact-emerging

FDA 更新了开发治疗和预防 COVID-19 的小分子药物和生物制品的指南

链接：https://www.fda.gov/media/137926/download

编者注：药明康德公众号 2021 年 2 月 24 日重点就 FDA 对疫苗的相关指南做了详细解读

参考链接：https://mp.weixin.qq.com/s/LsyN5DiwRuY4M_Kqwy-ZwQ