**编号：YY015-20221226001**

**标题：US public health services receive $3bn to build workforce and tackle local needs**

**简介：**The US Centers for Disease Control and Prevention (CDC) has awarded $3.2bn to strengthen the US public health system, the first time it has made such an award.1The funds, which come mostly from the American Rescue Plan Act, will be given directly to help state, local, and territorial governments across the US improve their public health workforce and infrastructure. The CDC said that everyone in the US lives in a district that will receive funding under this new grant.

**全文链接：**https://www.bmj.com/content/379/bmj.o2914

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**标题：Audit of Data Sharing by Pharmaceutical Companies for Anticancer Medicines Approved by the US Food and Drug Administration**

**简介：**IMPORTANCE Emerging policies drafted by the pharmaceutical industry indicate that they will transparently share clinical trial data. These data offer an unparalleled opportunity to advance evidence-based medicine and support decision-making. OBJECTIVE To evaluate the eligibility of independent, qualified researchers to access individual participant data (IPD) from oncology trials that supported US Food and Drug Administration (FDA) approval of new anticancer medicines within the past 10 years. DESIGN, SETTING, AND PARTICIPANTS In this quality improvement study, a cross-sectional analysis was performed of pivotal clinical trials whose results supported FDA-approved anticancer medicines between January 1, 2011, and June 30, 2021. These trials' results were identified from product labels. EXPOSURES Eligibility for IPD sharing was confirmed by identification of a public listing of the trial as eligible for sharing or by receipt of a positive response from the sponsor to a standardized inquiry. MAIN OUTCOMES AND MEASURES The main outcome was frequency of IPD sharing eligibility. Reasons for data sharing ineligibility were requested and collated, and company-, drug-, and trial-level subgroups were evaluated and presented using chi(2) tests and forest plots. RESULTS During the 10-year period examined, 115 anticancer medicines were approved by the FDA on the basis of evidence from 304 pharmaceutical industry-sponsored trials. Of these trials, 136 (45%) were eligible for IPD sharing and 168 (55%) were not. Data sharing rates differed substantially among industry sponsors, with the most common reason for not sharing trial IPD being that the collection of long-term follow-up data was still ongoing (89 of 168 trials [53%]). Of the top 10 anticancer medicines by global sales, nivolumab, pembrolizumab, and pomalidomide had the lowest eligibility rates for data sharing (<10% of trials). CONCLUSIONS AND RELEVANCE There has been a substantial increase in IPD sharing for industry-sponsored oncology trials over the past 5 years. However, this quality improvement study found that more than 50% of queried trials for FDA-approved anticancer medicines were ineligible for IPD sharing. Data accessibility would be substantially improved if, at the time of FDA registration of a medicine, all data that support the registration were made available.

**全文链接：**https://pan.ckcest.cn/rcservice//doc?doc_id=108573

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**标题：Clinical pharmaceutical screening in critical situations in a radioiodine therapy management service**

简介：Radioiodine therapy can be used in differentiated thyroid carcinoma and requires extensive evaluation to ensure effectiveness and safety. Therefore, it is necessary to evaluate all health problems and medications used in the pre-radioiodine therapy period and comprehensive medication managementservices can serve as a screening tool in this context. The present study aims to describe critical clinical situations identified during the initial assessments of a comprehensive medication management service offered to differentiated thyroid carcinoma patients pre-radioiodine therapy, and the pharmaceutical interventions performed to solve them. A descriptive study with regard to the initial ten months of a comprehensive medication management service was carried out in a large oncology hospital (Rio de Janeiro, Brazil). Descriptive analysis was used to describe the critical clinical situations identified, as well as the correspondent drug therapy problems and the type, acceptability, and outcomes of the pharmaceutical interventions performed to solve them. Thirty patients with an average of 45.8 years and 5.1 medications were evaluated. Five critical clinical situations were identified; corresponding to drug therapy problems two(needs additional drug therapy - n = 4) and drug therapy problems four (dosage too low - n = 1). All pharmaceutical interventions were accepted. The comprehensive medication management service provision pre-radioiodine therapy is feasible and represents an important screening strategy.
全文链接：https://pan.ckcest.cn/rcservice//doc?doc_id=108575

**编号：YY015-20221226004**
**标题：German Pharmaceutical Pricing: Lessons for the United States**
简介：To control pharmaceutical spending and improve access, the United States could adopt strategies similar to those introduced in Germany by the 2011 German Pharmaceutical Market Reorganization Act. In Germany, manufacturers sell new drugs immediately upon receiving marketing approval. During the first year, the German Federal Joint Committee assesses new drugs to determine their added medical benefit. It assigns them a score indicating their added benefit. New drugs comparable to drugs in a reference price group are assigned to that group and receive the same reimbursement, unless they are therapeutically superior. The National Association of Statutory Health Insurance Funds then negotiates with manufacturers the maximum reimbursement starting the 13th month, consistent with the drug's added benefit assessment and price caps in other European countries. In the absence of agreement, an arbitration board sets the price. Manufacturers accept the price resolution or exit the market. Thereafter, prices generally are not increased, even for inflation. US public and private insurers control prices in diverse ways, but typically obtain discounts by designating certain drugs as preferred and by restricting patient access or charging high copayment for nonpreferred drugs. This article draws 10 lessons for drug pricing reform in US federal programs and private insurance.
全文链接：https://pan.ckcest.cn/rcservice//doc?doc_id=108577

**编号：YY015-20221226005**
**标题：Medication not accounted for in hospital electronic medication administration records: a retrospective observational study**
简介：Abstract Objective To determine the nature, extent, and cost of discrepancies between the quantities of medications supplied to medical departments and administered to patients in public hospitals. Design Multicentre, retrospective observational study; analysis of electronic

pharmacy drug management system (medication supply) and medication administration data for twenty frequently used medications. Setting, participants Medical, surgical, and emergency department (ED) wards in each of four public hospitals in Melbourne, Victoria, during the 2019 calendar year. Main outcome measures Discrepancy between the quantity of medication supplied and administered to patients (as proportion of medication supplied), overall and by hospital and ward type; direct cost to the hospitals of the discrepancies. Results The overall discrepancy rate (all medications, hospitals, ward types) was 19.2% (95% CI, 19.0–19.4%); overall rates by hospital ranged from 5.8% (95% CI, 5.7–5.9%) to 26.7% (95% CI, 26.6–26.9%). The discrepancies were largest for medications useful for self-treatment: oral antibiotics (eg, phenoxymethylpenicillin 250?mg capsule, 86.8%; 95% CI, 83.1–89.9%) and gastrointestinal medications (eg, ondansetron 4?mg tablet, 53.3%; 95% CI, 52.9–53.7%). Discrepancies were larger for oral than equivalent (or similar) parenteral formulations; they were generally low for controlled medications (temazepam, diazepam, oxycodone). Overall discrepancies were larger for EDs (32.3%; 95% CI, 32.2–32.5%) than for admitted patient wards, but differed between EDs (range: 25.7%; 95% CI, 25.5–26.0% to 39.5%; 95% CI, 39.2–39.7%). The estimated direct cost to hospitals of the discrepancies for the selected medications was $27?800. Conclusion Substantial quantities of medications supplied to hospital wards and EDs are not accounted for in electronic administration records.

**全文链接：**https://pan.ckcest.cn/rcservice//doc?doc_id=108576

**编号：YY015-20221226006**

**标题：UK pharmaceutical manufacturers urged to review data integrity systems**

**简介：**During the past 20 years,improvements in processing power have fundamentally changed pharmaceutical manufacturing.Now,businesses can monitor,analyse and model far more data than ever before,which has led to significant advances in drug discovery and development.Automated machinery has also allowed production to expand at an unprecedented scale.However,as systems advance,there is a growing threat to data integrity.The previous two decades are arguably defined as much by regulatory oversights and human error as they are by advances in technology.For example,in 2019 in the US,the US Food and Drug Administration(FDA)issued more than 90 warning letters.One study that analysed FDA letters in the US between 2007 and 2018 found that most were issued for failing to follow and maintain correct procedures or poor documentation practices.The same study concluded that cases of required action were on the wane...and a growing number of businesses were compliant with stricter industry guidance.Although this is clearly positive news,it's also a situation that cannot stay the same.Data integrity is an ongoing process,rather than a static state,and requires businesses to be aware of potential threats ahead of production.

**全文链接：**https://pan.ckcest.cn/rcservice//doc?doc_id=108578