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DRUG REPURPOSING IN THE ERA OF ARTIFICIAL INTELLIGENCE: FROM MOLECULAR INSIGHTS TO CLINICAL TRANSLATION

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ABSTRACT

Drug repurposing, also known as drug repositioning or reprofiling, is the strategy of identifying new therapeutic indications for existing, approved, or investigational drugs outside their original scope of use. This approach offers a faster, lower-cost, and lower-risk alternative to de novo drug discovery because repurposed candidates already possess established pharmacokinetic, pharmacodynamic, and safety profiles. This review summarises the pharmacological and biological mechanisms that underlie drug repurposing, including target receptor interaction, pathway modulation, genomic and proteomic insight, and disease-mechanism overlap, and outlines the growing role of computational approaches such as artificial intelligence, machine learning, and network pharmacology in candidate identification. Representative case studies from the COVID-19 pandemic, including hydroxychloroquine, remdesivir, tocilizumab, captopril, and azithromycin, illustrate how existing drugs were rapidly redeployed during a public health emergency, while examples such as mifepristone and metformin demonstrate the regulatory and intellectual property challenges that repurposing efforts continue to face. The review further discusses clinical, regulatory, and economic barriers that limit the translation of computationally predicted candidates into approved therapies. It is concluded that drug repurposing has evolved from an opportunistic, serendipitous practice into a structured, data-driven discipline, and that its full potential will depend on harmonised regulatory pathways, open-access clinical data sharing, and sustained public-private investment.

KEYWORDS: Drug repurposing; Drug repositioning; Computational drug discovery; COVID-19 therapeutics; Network pharmacology; Regulatory challenges.

INTRODUCTION

The process of employing a current medication or therapeutic candidate for a novel treatment or medical condition for which it was not previously indicated is known as "drug repurposing."[1] Drug repurposing is a method that seeks new therapeutic uses for authorized medications or current candidates that differ from their original usage.[2] Drug repurposing, sometimes referred to as drug repositioning or reprofiling, is the process of finding new therapeutic applications for currently available medications outside of their original indications. This strategy can help manage epidemics, speed up drug research, and unleash the potential of currently available medications for other illnesses, and it has already produced some notable examples.

One of the most well-known instances of an established medication finding a new use is remdesivir. It was first developed to combat Ebola, but scientists swiftly turned to it when COVID-19 struck the globe; it was studied in COVID-19 patients and ultimately received emergency approval to treat them because it prevents the virus from

replicating.[3] Dexamethasone, used for decades to treat inflammation and swelling, is not a novel or sophisticated medication; however, it proved to be one of the most effective tools available during the COVID-19 pandemic,[4] dramatically reducing the frequency of deaths when administered to critically ill patients who required oxygen or were on ventilators. The primary purpose of baricitinib was to treat rheumatoid arthritis, a disease in which the body's own joints are attacked by the immune system; sometimes COVID-19 causes the immune system to go into overdrive, a phenomenon known as a "cytokine storm" that damages the lungs and other organs, and researchers discovered, with the aid of artificial intelligence, that baricitinib could reduce this overreaction, increasing the number of hospitalized COVID-19 patients who survived when combined with other common medications like dexamethasone.

The range of repurposing has significantly increased in the modern era. Repurposing dimethyl fumarate, chloroquine, and daptomycin to address a variety of medical needs beyond their original indications are successful instances. This field is also rapidly changing due to the power of artificial intelligence;[5] drug repurposing finds new therapeutic uses for existing drugs that were initially developed for different indications in an effort to capitalise on the established safety and efficacy profiles of known drugs, and AI now helps predict which drugs are most likely to succeed with previously unheard-of accuracy.[6] The increased confidence in this strategy is reflected in the worldwide medication repurposing industry, which is estimated to be worth USD 35.3 billion in 2024 and is expected to reach USD 51.8 billion by 2032. In response, regulatory authorities have established simplified clearance processes, such as the FDA's 505(b)[2] pathway. Drug repurposing is not only a scientific shortcut but also a humanitarian, pragmatic, and urgent necessity in a world where new pandemics might appear overnight, rare diseases continue to go untreated, and healthcare systems are under pressure due to growing expenses.

More precise identification of medication repurposing candidates for further clinical study has been made possible during the past ten years by developments in genetic profiling, database curation, and machine learning techniques.[7]

MECHANISMS OF DRUG REPURPOSING

Drug repurposing involves a number of processes that make it easier to find novel therapeutic applications for already-approved medications. Pharmacological and biological routes can be used to broadly classify these mechanisms.

1. Pharmacological Mechanisms

The use of a drug's current pharmacodynamics and pharmacokinetics to target novel ailments is known as a pharmacological mechanism. This comprises

Target Receptor Interaction: A lot of medications work by attaching themselves to particular receptors. Researchers can find novel therapeutic targets by comprehending the receptor characteristics of currently available medications. For instance, because it interacts with serotonin receptors that affect tumour growth, the antidepressant fluoxetine has been used to treat some forms of cancer.[8]

Pathway Modulation: Drugs can modulate biochemical pathways that are implicated in various diseases. For instance, the anti-inflammatory drug celecoxib has been repurposed for cancer treatment based on its ability to inhibit the COX-2 pathway, which is involved in tumorigenesis.[9]

2. Biological Mechanisms

Biological mechanisms focus on the understanding of disease biology and how existing drugs can be repositioned based on biological similarities between diseases.

Genomic and Proteomic Insights: The discovery of biomarkers and molecular signatures that might forecast medication success in many illnesses has been made possible by developments in genomics and proteomics. Because it affects cellular metabolism pathways important to tumour growth, this strategy has led to the repurposing of the antidiabetic medication metformin in cancer therapy.[10]

Disease Mechanism Overlap: Some diseases share common biological pathways. For example, the antiviral drug ribavirin has been explored for use in treating multiple sclerosis due to its immunomodulatory effects.[11]

3. Computational Methods

Drug repurposing has changed as a result of the integration of computational technologies, which make it possible to analyse vast databases and identify possible drug-disease correlations.

AI and Machine Learning: Algorithms can examine current data to spot trends and forecast novel medicinal applications. AI, for instance, has been used to forecast the effectiveness of current medications against COVID-19, resulting in the quick selection of candidates for clinical trials.[12]

Network Pharmacology: This method looks at how medications, targets, and illnesses interact inside biological networks. Researchers can find novel therapeutic uses for currently available medications by charting these interactions.[13]

CASE STUDIES

Repurposed agents may be classified into four main categories:[14]

- "Old" antivirals and non-antiviral agents showing certain inhibitory activity against SARS-CoV-2 (e.g., hydroxychloroquine, lopinavir/ritonavir, remdesivir, colchicine).
- Medications that were first created and authorised to treat idiopathic pulmonary fibrosis or severe chronic obstructive pulmonary disease (COPD), such as pirfenidone and phosphodiesterase-4 (PDE-4) inhibitors.
- Dietary supplements, nutraceuticals, micronutrients, and herbal remedies that have been repurposed as COVID-19 adjuvant therapy.
- Gas mixtures (such as nitric oxide or ozone auto-hemotherapy).

By preferentially directing extracellular zinc to intracellular lysosomes, hydroxychloroquine demonstrates zinc ionophore characteristics that impede RNA-dependent RNA polymerase activity and coronavirus replication. Ten trials have been registered on ClinicalTrials.gov to investigate the concept that association with zinc supplementation may increase the inhibitory action of hydroxychloroquine on SARS-CoV-2 replication.[15]

Remdesivir is a prodrug that was initially created for the Ebola outbreak. It is available only as an intravenous formulation of a nucleotide analogue that is intracellularly converted to an analogue of adenosine triphosphate, blocking viral RNA polymerases.[16] Remdesivir is anticipated to have low tissue distribution and penetration, particularly into the lung, and to achieve insufficient pulmonary concentrations in comparison to the IC50 for SARS-CoV-2, based on physicochemical/pharmacokinetic characteristics and preclinical evidence, when taken as prescribed (200 mg loading dose followed by 100 mg daily for 5–10 days).[17] Direct pulmonary delivery has been proposed to increase lung concentrations of remdesivir and its active metabolites in COVID-19 patients, possibly at a dose that is 4–10 times lower; however, pulmonary delivery of remdesivir may only be effective in patients who continue to breathe spontaneously and have sufficient pulmonary function, which presents a greater challenge in cases of severe respiratory failure requiring respiratory assistance.[18]

Tocilizumab targets the interleukin-6 receptor (IL-6R) and is a humanised monoclonal antibody (MoAb). The well-established pharmacology, pharmacokinetics, clinical efficacy, safety, and role of tocilizumab in rheumatoid arthritis (RA) may also be attributed to its impact on the AKT/mTOR pathway.[19] By preventing IL-6, one of the cytokines most implicated in this process, from binding to its receptor, this MoAb successfully avoids the large cytokine release syndrome seen in severe COVID-19 without exerting any direct antiviral effect.[20] A phase III randomised, double-blind, placebo-controlled trial to evaluate tocilizumab's efficacy in hospitalised patients with severe COVID-19 pneumonia was approved by the FDA.[21]

Captopril, a powerful and competitive ACE2 inhibitor, is typically used to treat hypertension. Studies in animals show that it can reduce kidney damage and inflammation,[22] and randomised clinical trials for the treatment of COVID-19 have advanced to phase III (NCT04345406).[23] Captopril's ability to prevent acute respiratory distress syndrome (ARDS), which is frequent in COVID-19 patients, was also the subject of recently completed clinical research, although the findings have not yet been published; it has additionally been observed to have detrimental pulmonary effects in COVID-19 patients with diabetes (NCT04355429).[24,25]

The macrolide antibiotic azithromycin has other characteristics, such as the generation of antiviral interferons (IFNs), that may justify its use in viral infections.[26] In contrast to the macrolides erythromycin and telithromycin, as well as almost half of the 225 novel macrolides examined, azithromycin doubles the amounts of antiviral type-I and type-III IFN produced by virus-infected bronchial epithelial cells.[27] Macrolides also possess anti-inflammatory properties that could ameliorate COVID-19 and, being antibiotic in nature, could help prevent secondary bacterial infection; azithromycin may additionally have an antiviral effect against SARS-CoV-2, according to a drug-screening publication.[28]

MODERN APPROACHES IN DRUG REPURPOSING

Computational Approach

By finding new uses for already-approved medications, computational drug repurposing significantly lowers the time and expense of drug development. This approach increases the effectiveness of drug repositioning by enabling the collaborative examination of several data sources, such as genetic, biological, and pharmacological data.[29] Modern computational drug discovery uses several methods and strategies, including AI, machine learning, network models, and text mining and semantic inference, along with strategies such as target-based drug repurposing, pathway-based drug repurposing, target mechanism-based drug repurposing, phenotype-based repurposing, and signature-based repurposing.[30]

Ligand-level approach: medications are initially encoded into fixed-length chemical representations in ligand-based repurposing, and candidates are ranked according to predetermined similarity metrics based on how closely their representations resemble those of approved medications.[31] Quantitative structure–activity relationship (QSAR) models and molecular fingerprints link structural characteristics to pharmacological activity.[32] The breadth of ligand-based repurposing can be expanded by combining chemical descriptors with bioactivity data or gene-expression fingerprints to

identify mechanistically significant analogues that evade conventional structural clustering.[33]

Target-centric repositioning is an on-target repurposing approach that involves a nearby indication or an extension of an indication within the same therapeutic area. Finding new uses for a medication based on newly discovered targets is the foundation of drug-centric repurposing.[34] The drug–disease link of closely related indications is the main focus of disease-centric repurposing; creating a medication for combination therapy that combines two or more pre-existing molecules is a typical example of this strategy.[35]

CHALLENGES IN DRUG REPURPOSING

The market for repurposed therapies remains small because, despite its benefits, repurposing medications is quite challenging. Clinical repurposing studies require substantial financial investment, confirmation of safety requirements, efficacy verification, and marketing, compounded by a lack of patent protection.[36]

1. Clinical Challenges

Dosing and Formulation: The dosage, mode of administration, or formulation needed for the new indication may be entirely different from the original use. This may necessitate whole new pharmacokinetic and toxicological research,[37] reflecting the basic problem that pharmacological inhibitors frequently do not reproduce genetic alterations of the same targets.[38] Furthermore, despite significant advancements in computational methods, there remains no reliable correlation between algorithmic predictions and clinical performance, with many promising computational hits failing to demonstrate effectiveness in clinical settings.[39]

2. Regulatory Challenges

Intellectual property: a drug's secondary therapeutic mechanism enters the public domain and cannot be patented as a novel technique of use if it has already been casually described in medical literature or used off-label by clinicians.[40]

Example: Mifepristone (Korlym)

Mifepristone was first authorised as a single, one-time dose for emergency contraception. The required treatment plan changed to chronic, daily, long-term dosing when it was repurposed for Cushing's syndrome. Owing to the significant shift in exposure length, the US FDA could not accept the previous safety data; to close the data gap, the company had to carry out additional, expensive long-term animal toxicity and clinical safety investigations.[41,42]

Metformin (TAME trial): through the Targeting Aging with Metformin trial, researchers have attempted to formally repurpose the diabetes medication metformin to target aging and age-related multimorbidity.[43] The FDA and other regulatory agencies do not accept "aging" as a legitimate, treatable illness; in the absence of a pre-established, regulated clinical endpoint for aging, researchers had to engage in years of regulatory negotiations to create a suitable composite endpoint that regulators would assess for efficacy.[43]

DISCUSSION

Drug repurposing is now an organised, predictive science rather than an accidental discovery process, owing to the incorporation of cutting-edge data-processing techniques. The main benefit of this approach is its speed and adaptability in public health emergencies, as demonstrated by the rapid deployment of remdesivir, dexamethasone, and baricitinib during the COVID-19 pandemic.[44] Researchers can expedite the early stages of drug development by utilising machine learning, network pharmacology, and established safety standards. However, a persistent data deficit becomes apparent when a computational model is translated into clinical practice: even when early-stage toxicity profiling is well developed, substantial modifications to dosage, treatment duration, or delivery method necessitate further regulatory review.[45] The field also faces an economic conundrum, as the absence of strong intellectual property protection frequently results in widespread off-label replacement once a low-cost, off-patent generic medication is effectively repurposed.[46] Many scientifically promising candidates consequently remain confined to academic laboratories because developers are unable to recover the substantial costs of validating Phase III clinical trials.

CONCLUSION

In contemporary medicine, drug repurposing is a practical and humanitarian requirement, particularly for treating neglected rare diseases and rising pandemics. However, its potential remains limited when reliance is placed solely on market forces and conventional regulatory procedures. To maximise the global value of this strategy, international regulatory bodies must establish more unified and flexible submission pathways, such as expanded data exclusivity for generic modifications. Redundant trial designs can be eliminated by dismantling corporate data silos through open-access clinical archives. Predictive algorithms must ultimately be translated into easily accessible, bedside treatments through a well-balanced combination of public–private funding mechanisms and improved regulatory incentives.

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