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A Review on Drug Repurposing: A Functional Instrument for Contemporary Drug Delivery

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ABSTRACT:In pharmaceutical research, **Drug repurposing**, sometimes referred to as drug repositioning, is a strategic approach that finds novel therapeutic applications for already approved medications. The time, expense, and risk involved in traditional drug development are greatly decreased by using compounds that have already undergone thorough safety and pharmacokinetic analyses. Due to its potential to address unmet medical needs, particularly in rare, neglected, and emerging diseases, repurposing has gained momentum. Big data analytics, artificial intelligence, and computational biology advancements have made it possible to screen drug libraries systematically in order to find new indications. **Drug repurposing** has potential, but it also has drawbacks, including restrictions on intellectual property, legal restrictions, and the requirement for thorough clinical validation. However, it continues to be an effective tool for increasing therapeutic options and speeding up drug discovery.

KEYWORDS: Drug repurposing, clinical trials, molecular docking, drug discovery, post-market safety

I. INTRODUCTION

The process of employing a current medication or drug candidate for a new medical disease or treatment for which it was previously not recommended is known as **drug repurposing**.[1] Originally, it was created to treat a different illness. Some have referred to it as an unplanned, serendipitous process. For instance, Pfizer repurposed sildenafil citrate, which was once created as an antihypertensive medication, to treat erectile dysfunction based on retrospective clinical experience, which resulted in enormous global sales.

It is particularly useful where traditional de novo drug development is not cost-effective, or a cure is urgently needed, such as in the search for a COVID-19 treatments. The goal of drug repurposing is to quickly identify compounds with an established safety profile and known therapeutic advantages that may prove efficacious for other indications. Pharmaceutical companies are undertaking drug repurposing projects for rare diseases, oncology, infectious and autoimmune diseases and more. Pharmacies are working on repurposing drugs for a variety of conditions, including autoimmune, infectious, and uncommon diseases as well as cancer.

Fig.1 Drug Repurposing

Drug repurposing offers numerous advantages in clinical trials, including accelerated timelines, reduced costs, increased success probabilities, and expanded therapeutic options.

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II. DRUG DISCOVERY VS DRUG REPURPOSING

Through a significant reduction in the time, expense, and dangers involved with traditional drug research, drug repurposing provides a strategic advantage. Advances in cheminformatics, bioinformatics, and artificial intelligence have made repurposing a more practical strategy for speeding up medication development.

Traditional Drug Discovery

Traditional drug discovery is the process of creating new molecular entities (NMEs) from scratch to treat specific diseases. It follows a five-stage path: [2]

1. **Discovery & Preclinical Research** – Scientists identify potential drug candidates and test them in labs.
2. **Safety Review** – Initial screening ensures the drug is not toxic.
3. **Clinical Research** – The drug undergoes human trials to assess efficacy and safety.
4. **FDA Review** – Regulatory bodies evaluate the results for approval.
5. **Post-Market Safety Monitoring** – Even after approval, the drug is continuously monitored for side effects.

Drug Repurposing

Drug repurposing (or repositioning) focuses on finding new uses for existing drugs. Since these drugs already have established safety profiles, the process is faster and more cost-effective. It consists of four stages:[3]

1. **Compound Identification** – Scientists search for existing drugs with potential new applications.
2. **Compound Acquisition** – The selected drug is studied further.
3. **Development** – The drug undergoes clinical trials for its new use.
4. **Post-Market Safety Monitoring** – Ensuring safety for the new indication.

III. IMPORTANCE OF DRUG REPURPOSING

Here's why it's important:

- **Faster Development:** Since repurposed drugs have already been tested for safety, their approval process is much quicker than new drug development, which can take years or even decades.
- **Cost-Effective:** Developing a new drug is extremely expensive, but repurposing an existing drug can significantly reduce costs, making treatments more accessible.
- **Addresses Unmet Medical Needs:** Some diseases, especially rare ones, lack effective treatments. Repurposing drugs can offer new solutions for conditions that have few or no options.
- **Improved Success Rates:** Since existing drugs have known effects and established safety profiles, repurposing them is less risky than developing a completely new drug.
- **Pandemic and Emergency Response:** During crises like COVID-19, repurposing drugs was essential for finding treatments quickly, rather than waiting for new drugs to be developed.
- **Overcoming Antibiotic Resistance:** Many bacteria are developing resistance to existing antibiotics. Repurposing old drugs can help discover new treatments for resistant infections.

IV. APPROACHES OF DRUG REPURPOSING

Compared to developing new medications from scratch, drug repurposing saves money and time, making it a useful tactic.Approaches to drug repurposing can be generally divided into:

1. Serendipity
2. Hypothesis – Driven Approaches:

- Experimental Approach
- Computational Approach (also known as in silico drug repurposing)

1.SERENDIPITY

Accidental or chance drug discovery is not new. Sildenafil (Viagra), a PDE-5 inhibitor that was first created by Pfizer as an antianginal medication in the 1990s, is among the most well-known instances. Researchers saw its effectiveness in treating erectile dysfunction throughout clinical trials. As a result, Viagra gained widespread prescriptions for erectile dysfunction after being approved in 1998. Later, in 2005, the medication was licensed under the trade name Revatio for the treatment of pulmonary arterial hypertension.

2.HYPOTHESIS – DRIVEN

Experimental Approach

This method entails finding substances that cause discernible alterations in animal illness models or in vitro cell lines.[4]

For instance, among 1,120 chemicals, the antipsychotic medication pimozide and the

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selective oestrogen receptor modulator tamoxifen, which is used to treat breast cancer, were evaluated for their capacity to stop the growth of Toxoplasma gondii in infected cells. Although more research is needed to prove their effectiveness, both medications demonstrated encouraging antiparasitic benefits. [5]

Computational Approach

With the use of specialized software, researchers may analyse high throughput biological data about a variety of disorders. Computational drug repurposing canbe further separated into:[6]

i. Target-Based Strategy
ii.Drug-CenteredStrategy
iii. Network-Based Method
iv. Signature-Based Method

i.Target-Based Strategy:[7]

The receptor or protein that a drug acts through determines which disease it is associated with. It falls under the following categories:

a. On-Target Repurposing
b.Off – Target Repurposing

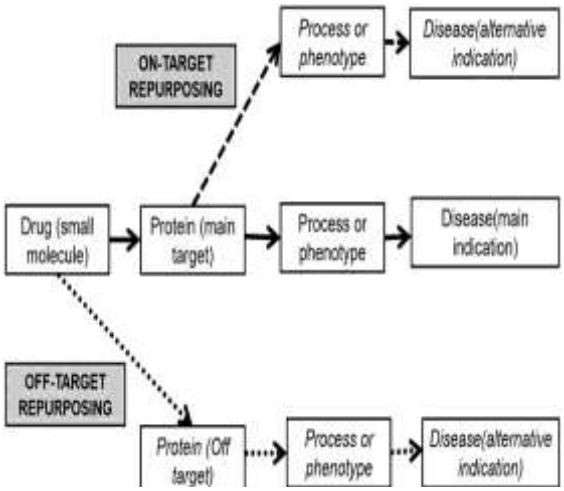

Fig.2 On and Off – Target Repurposing.

ii.Drug-CenteredStrategy:

Drugs that act on many targets within a single disease pathway or multiple pathways across different diseases are the focus of this strategy.[8] Typically, we begin with a sickness and then look for medications to treat it. We take the opposite approach with a drug-centric approach. We begin with the medication and then determine which diseasesit can treat. For instance: Because its target proteins, VEGF and PDGF, were shown to be implicated in tumour angiogenesis, sunitinibwhich was first licensed for GIST and renal cell carcinomawas later repurposed for pancreatic neuroendocrine tumours.

iii. Network-Based Method:

Drugs, diseases, and gene products will constitute the nodes of the network in a network-based approach, and interactions between the three will serve as the linkages between the nodes. Drug-drug, drug-disease, disease-disease, drug-gene, and disease-gene are examples of interactions. This method, which is founded on the association principle, can uncover undiscovered connections between a medication and illness, laying the groundwork for drug repurposing.[9]

For instance: Through Subnetwork Enrichment Analysis, fulvestrant, an oestrogen receptor down regulator used to treat breast cancer, was discovered to have the potential to treat glioblastoma by connecting its inhibitory effects to Cyr61, a protein related to angiogenesis.

iv. Signature-Based Method

This approach examines gene changes and patterns of protein expression to investigate molecular-level processes.[10]Drug-specific gene expression profiles can be compared to disease-related gene signatures using the Connectivity Map (CMap), a database created at the Broad Institute.

CMap makes it possible to:

• Find links between medications, genes, and illnesses.
•Forecasting potentially useful substances for medication repurposing.

The steps involved in CMap analysis are as follows:

• A list of genes believed to be associated with a specific disease is entered into the database.
• The result is a list of medications with presumed efficacy for that condition.
• Finding links between medications, genes, and illnesses
• The ability to predict potentially therapeutic substances, which serve as the foundation for drug repurposing.

For instance: CMap analysis identified **Vorinostat**, an FDA-approved histone deacetylase (HDAC) inhibitor for cutaneous T-cell lymphoma, as a potential therapeutic agent for gastriccarcinoma.

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V. CHALLENGES OF DRUG REPURPOSING

One novel strategy is repurposing, however the claims that it will be quicker, safer, and more efficient are not universal and call for a scientific evaluation of each situation separately. The primary obstacles to medication repurposing are as follows:

• Database Selection & Compound Availability: It can be difficult to find a trustworthy drug molecule from a carefully curated database; accuracy requires access to a reputable vendor.
• Intellectual Property & Patent Considerations: Obtaining patent approval frequently calls for changes to the drug's formulation or strength, which may affect how effective it is.
• Regulatory Challenges: The regulatory process may encounter obstacles due to a newly proposed indication's potential lack of enough safety data and the need for strong evidence to secure approval under the 505(b)(2) application, which is comparable to an NDA.
• Affordability Problems: Exorbitant clinical trial expenses can be costly, especially for uncommon disorders. Costly Proof of Concept (PoC) studies are required for regulatory approval, which makes them unaffordable for nonprofit groups, small biotech companies, and academic researchers.
• Safety Concerns: Consistent dosage and administration methods are essential, even though the safety profile of an approved medication is often documented.
• Physiological Variability: Repurposed medications frequently target a variety of patient populations with unique physiological characteristics, which raises the possibility of unanticipated side effects that require careful assessment.
• Regulatory Challenges: It might be difficult to obtain approval for drug repurposing within set timeframes and legal frameworks.
• Disease Complexity: Drug target identification is challenging due to pandemics, patient population variability, and the unknown mechanisms behind diverse diseases.
• Expertise Gaps: Inadequate understanding among rare disease nonprofits may hinder successful efforts torepurpose drugs.
• Tool Validation: Because software programs use different approaches and scoring systems, which could produce inconsistent findings, it is important to critically evaluate the verification and validation of computational tools employed in drug repurposing. For instance, because to phospholipidosis, antiviral test findings obtained in vitro could not transfer well to in vivo applications.

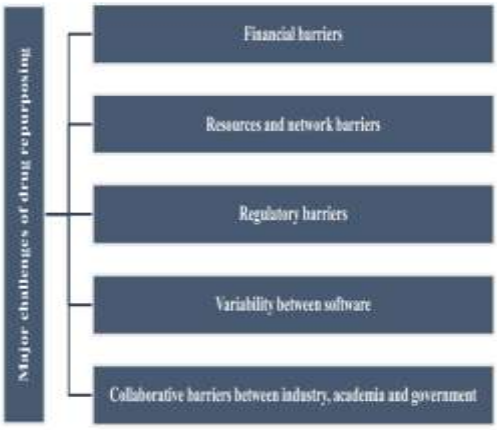

Fig.3 Challenges in Drug Repurposing

VI. ETHICAL AND SOCIAL CONSIDERATIONS OF DRUG REPURPOSING

Providing fair access to these therapies for all patient populations is a crucial ethical factor in medication repurposing. Even while reused medications may be less expensive than brand-new treatments, access inequalities may still exist, especially in underprivileged or marginalized populations. [11,12] Important ethical guidelines in drug repurposing research include preserving patient autonomy and gaining informed consent. Participants in these trials must be made fully aware that the medication is being used off-label, which means it has not yet received approval for the intended use. Additionally, they must be informed of the possible dangers, advantages, and unknowns of repurposed treatments, and their consent must be freely provided and unassisted.[13]

Maintaining the ethical integrity of drug repurposing trials and protecting patient welfare require strict safety monitoring and strong regulatory control. When it comes to analyzing supporting data, judging the caliber of clinical trial results, and keeping an eye on post-market safety and efficacy, regulatory bodies are essential.[14] To strengthen the ethical and scientific legitimacy of drug repurposing research, transparency and data sharing are essential. Public trust and accountability are eventually fostered by open access to clinical trial data and conclusions, which promotes independent evaluation, result

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replication, and wider participation in scientific discourse.[15] Another ethical dilemma in medication repurposing is resolving conflicts of interest, particularly those brought on by financial incentives in the pharmaceutical sector.

VII. APPLICATIONS

1. Quick Reaction to New Illnesses:

Responding to pandemics and outbreaks is one of the most important uses of drug repurposing. In order to fight new infectious diseases, scientists frequently turn to established medications with established safety profiles because developing new treatments takes years. The COVID-19 pandemic served as a perfect illustration, as drugs such as remdesivir and dexamethasone were repurposed to treat patients, offering more rapid therapeutic choices while vaccines were being developed.

2. Economical Drug Development:

Conventional drug discovery is a costly process that frequently costs billions of dollars. The development process is greatly accelerated because repurposed medications have previously undergone comprehensive safety testing. Pharmaceutical companies find this approach appealing as it reduces financial risk while increasing the chances of obtaining a marketable product.

3.Treatment for Cancer:

It has been discovered that several non-oncology medications contain anti-cancer qualities. Through drug repurposing, researchers can investigate the potential of drugs originally created to treat diseases like diabetes or hypertension to stop the growth of tumors. One example is the diabetes medication metformin, which has demonstrated promise as an anti-cancer treatment because of its capacity to target the metabolism of cancer.

4.Personalized Healthcare and AI Coordination:

Drug repurposing is now even more accurate thanks to developments in genomic medicine and artificial intelligence. Customized treatments based on each patient's unique biology are possible because to AI-driven analysis that can predict how current medications will interact with various genetic profiles. This method is especially useful in oncology, where artificial intelligence (AI) can be used to find repurposed medications that target certain cancer cell mutations.

5.Antimicrobial Resistance:

Researchers are looking into repurposing older medicines or even non-antibiotic medications with antimicrobial qualities due to the growing threat of antibiotic-resistant illnesses. There are now more options for treating resistant bacterial strains without the need for brand-new antibiotics thanks to the antibacterial properties of some statins and antidepressants.

VIII. CONCLUSION

The process of developing new drugs is intricate and resource-intensive, requiring large sums of money, a great deal of research, qualified staff, and a lot of time. Only a small percentage of therapeutic candidates make it to Phase III trials, and even fewer make it to Phase IV, despite intense efforts. The development process typically takes ten to fifteen years, and the financial investment might range from $150 million to several billion dollars. Only one of the roughly 10,000 molecules that are screened makes it to market. Pharmaceutical companies and sponsors are frequently hesitant to engage in the development of new drugs because of high attrition rates. In light of these difficulties, finding novel therapeutic uses for already-approved medications through pharmacological repositioning or repurposing is a viable substitute.This method works for medications that are already on the market, have been taken off the market in the past because of toxicities, or have stopped in different stages of development. **Repurposing** existing medications becomes an important tactic because epidemics and new microbial threats, like the SARS-CoV-19 outbreak, frequently leave little time for disease-specific therapies.

Several successful cases of repurposed drugs against COVID-19, tuberculosis, colorectal cancer, Alzheimer's disease, cervical cancer, and Parkinsonism highlight the potential of this approach, especially with advancements in artificial intelligence.

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