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Editorial

3D printing of medicines: benefits of personalization, regulatory challenges, and perspectives for healthcare optimization

Impressão 3D de medicamentos: benefícios da personalização, desafios regulatórios e perspectivas para a otimização do cuidado em saúde

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Contemporary medicine is undergoing a revolution driven by advances in digital and manufacturing technologies, with 3D printing at the heart of this transformation. In hospital settings, the ability to customize medications through 3D printing promises to significantly improve treatment outcomes by tailoring to the needs of each patient[1-3]. However, this technology not only redefines pharmaceutical production methods but also challenges regulatory concepts and established healthcare[4,5] practices.

Personalized therapy offers undeniable advantages in terms of therapeutic efficacy and patient safety, especially for groups that traditionally face challenges with standardized formulations, such as children and the elderly[3,6,7]. 3D printing of medicines, or additive manufacturing, allows for the precise fabrication of doses, shapes, and compositions tailored to patients' metabolic profiles, clinical conditions, and even personal preferences, which can also motivate adherence to outpatient treatments. This technology constructs objects layer by layer from digital[8] designs. Although there are various techniques, the most employed and promising for solid medications involve the heating and extrusion of solid materials (drug-containing polymeric filaments) or semi-solids[9-11].

One of the main benefits of 3D printing is its application in pediatrics, where dose precision and patient acceptability are crucial. Studies show that 3D-printed medications formulated in attractive formats and flavors for children minimize their resistance to treatment. The work of Goyanes and collaborators (2019) pioneered the exploration of 3D printing to create pharmaceutical forms specifically designed for children in hospital settings. In 2024, new research, in an expanded version developed by the same group, confirmed previous findings by demonstrating how aesthetically and palatably appealing gummy tablets increased adherence in younger[3,12] patients. Such formulations not only facilitate drug administration but can also be designed to control their release, considering children's faster metabolism or in pharmaceutical forms that can change shape after ingestion, adapting to the body's physiology.

Regarding the elderly, a group often facing multiple chronic conditions requiring polypharmacy, 3D printing has been explored in creating multi-layered drug delivery systems for sequential release of active ingredients and has proven useful in optimizing complex[14] therapeutic regimens and reducing healthcare[7] costs. Zheng and collaborators (2020) developed polypills that combined compatible[13] active ingredients and reduced associated medication burden and regimen complexity, often linked to high rates of medication errors and drug interactions. Khaled and collaborators (2015) also indicated the feasibility of printed tablets combining captopril, glipizide, and nifedipine with different release profiles for each active[6] ingredient.

Artificial intelligence (AI) and automation also play an increasingly central role in optimizing

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this technology. AI can be used to design complex and personalized pharmaceutical formulations, while automated systems can manage the production of these medications with greater efficiency and precision[15,16]. This not only improves the quality of printed medicines but also reduces costs, waste generation, and production time, aligning the technology with circular[17] economy models.

While the prospects are promising, many challenges remain on the horizon. The need for advanced infrastructure, specialized training for healthcare professionals, and modernization of regulatory barriers are some of the main obstacles to be addressed. However, these bottlenecks also represent opportunities for innovation and improvement in how medications are developed and administered.

Even though 3D printing offers control over the dosage and composition of medications, ensuring consistency in produced batches constitutes a significant technical challenge, given that precision and reproducibility are crucial for the manufacturing of medicines. Concerns about drug stability and validation of printing processes are also important technical barriers that need to be overcome through research aimed at ensuring safe and effective final products.

Both healthcare professionals and patients are key actors in the successful acceptance of this new technology. In this regard, there is a need for discussions with multidisciplinary teams about the advances and limitations of 3D[1,4] printing in different clinical contexts, while also involving and demonstrating the safety and efficacy of printed medications to users. Studies and pilot projects that aim to analyze the application of 3D printing in hospital pharmacies are fundamental to strengthening the debate and, at the same time, reducing resistance and expanding the boundaries of this new technology's use.

Finally, a fundamental point in this discussion is the regulatory aspects involved in the production, adoption, and use of this new technology. Recognizing that regulation is predominantly configured for traditional methods of drug manufacturing, modernizing and building new regulatory frameworks for the approval of 3D-printed medications will result in significant advances in their implementation and safe integration into the hospital environment. Peculiarities of this new technology, such as mass personalization, challenge standard protocols for clinical trials and quality control. In this sense, as the demand for personalized medications grows, the market tends towards a significant expansion of 3D printing and the creation of new collaborative-institutional arrangements aimed at improving regulatory governance among government and health institutions, research, pharmaceutical industries, and tech startups.

The path ahead is complex and challenging, but the potential rewards for healthcare are immense. This editorial invites the pharmaceutical community to reflect on the growth of 3D printing, regulatory and market barriers, and the expansion of pharmatechnical and clinical studies throughout Latin America.

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