

Open-Source Design of Medical Devices: A Useful Biomedical Engineering Tool for Developing Countries

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Medical devices play an important role in disease management and pose an increasing economic burden worldwide. Current commercially available medical devices are effective but, given their elevated cost, are unaffordable for most patients in low- and middle-income countries (LMICs). The open-source hardware approach is a relatively new design option for conceiving and distributing the comprehensive technical information required for building devices. Therefore, open-source enables free and unrestricted use of the know-how to replicate and manufacture a device or modify its design for improvements. This approach thus aims at implementing open-source solutions that will contribute to widespread low-cost medical device availability in LMICs [1].

To ensure feasible implementation in LMICs, the device design should be conceptualized by co-design with a local team of medical and technical professionals. Special focus on devices built using general-purpose, low-cost electronic components (e.g., transducers, actuators, microprocessor) available in the internet market (e.g., Amazon, Alibaba) and on mechanical pieces obtained from simple 3D printers ensure affordability. Device construction using the open-source technical information provided should require only basic tools and be implementable by personnel with relatively inexperienced engineering training levels. The device functionality should be tested and validated in clinical settings.

The open-source design is widely applicable to routine medical equipment since most commonly used medical devices are based on often simple technological principles, which originated decades ago and are no longer restricted by patents [2]. Examples (e.g., www.open-source-medical-devices.com) cover a wide range of applications, from a device aimed at improving wound healing, to respiratory ventilators, newborn incubators and a setting for heat shock reduction risk in infants. The development pathway of the approach and its practical expansion within LMICs face several challenges, namely to engage more interdisciplinary local teams of physicians and engineers, and to expand the routine practices leading to clinical trial approval by local hospital ethics boards to ensure patient safety. However, the already available experiences strongly suggest that the open-source approach is a viable procedure to facilitate access to life-saving treatments in LMICs.

References

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