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Summary

- The pre-development phase takes an idea to a concept with a business case for developing the device. Key elements include defining user needs, generating different concepts and their respective regulatory pathway, intellectual protection strategy, reimbursement model and overall commercialization strategy.
- The development phase is an iterative process that converts the concept into a product that is tested and evaluated through the verification and validation process, and ready for regulatory submission.
- Design Transfer is a set of procedures that are required to ensure that the device's design is correctly translated into production specifications and performing a market preference evaluation prior to a full scale product launch.
- Following product launch, the product enters the post-market activities phase, in which operations are scaled up to reach sales targets, the product is maintained and improved if possible, and strategies for product refresh, product extensions, seeking new markets.

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Surgical Device Development

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Topic Relevance by Timeline

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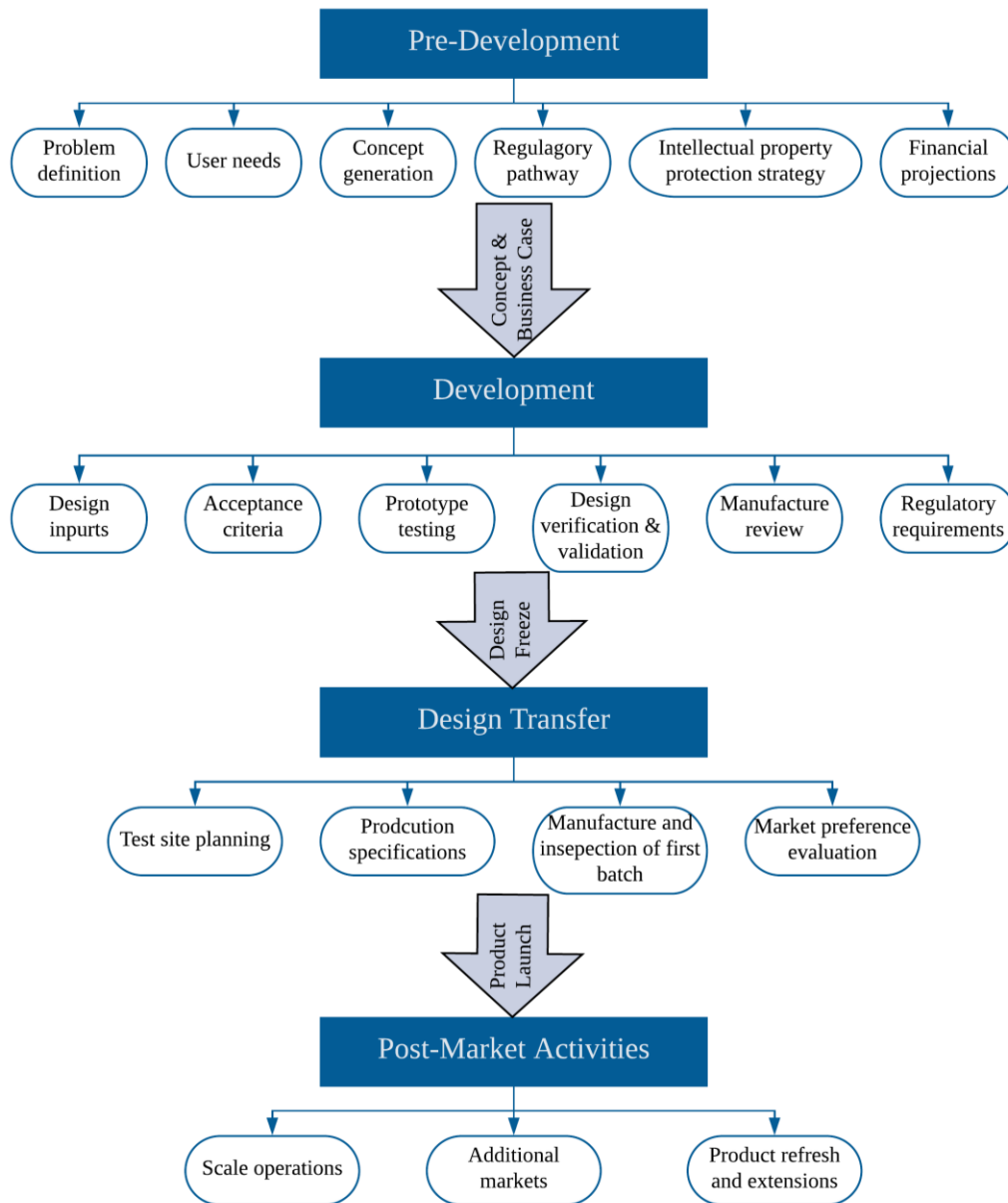
Introduction

Innovation in surgical systems is essential for continually moving the field forward to better address unmet patient needs. Academic medical centers have the mandate to treat patients and to advance healthcare, and thus play a pivotal role in the innovation process. They are contributors to the entrepreneurial landscape by incubating startup pharmaceutical and medical device companies to translate academic inventions into commercial products that result in societal impact.

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Figure 1. Medical Device Development Process.

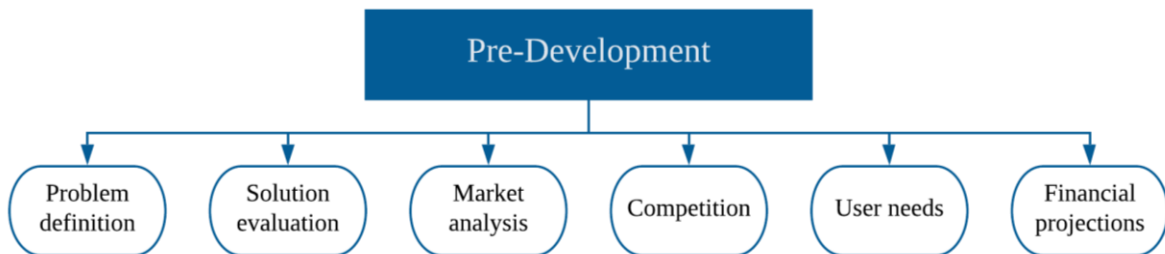
Bringing a new surgical device from a back-of-the-napkin sketch to clinical implementation is a disciplined process designed to maximize the potential for translation and commercialization success. Before prototyping and testing out device concepts, it is important to rigorously define the problem the device aims to address, clear indicators for success, and a scalable commercialization strategy. The entire process is shown in Figure 1 and will be discussed in detail in subsequent sections.

It is important to have a development process that are supported by appropriate design controls such as FDA CFR 820.30 and/or ISO 13485. Design controls should include an interrelated set of

best practises that make systematic assessments of the surgical device an integral part of the development process. This aides developers to identify deficiencies in design requirements and discrepancies between the proposed designs and requirements early in the process. Having a disciplined development process increases the likelihood that the final design transferred to production will translate into a device that is appropriate for its intended use and business model.

Pre-Development

Figure 2. Breakdown of Pre-Development Phase.



The first step in the pre-development phase of surgical device development is to clearly define the unmet need or problem that will be addressed with the new device (Figure 2). It is important to be able to state with some specificity the user need, where “user” could mean physician, nurse, patient, caregiver, hospital, health system, insurance company, or other stakeholders (Martin et al.). It is important to keep in mind for surgical devices, that the purchasing decision (i.e. hospital procurement committee), payor (i.e. health insurers), and end users (patients/clinicians) could be made by different entities. In many cases there are many hypotheses baked into a problem statement. It is recommended that the chapter on “Rapid Prototyping Strategies” be reviewed for tools and techniques on how to make explicit and validate these hypotheses. Specifically, contextual inquiry and prototyping are highly relevant for surgical device development. Keep in mind that healthcare is full of problems needing solutions. While many are purely clinical, such as curing diabetes, or rapidly diagnosing tuberculosis, most problems are in the “better, faster, cheaper” category. These problems need devices that improve an established intervention, make it more accessible, or improve the ability for providers to care for their patients in terms of time, efficiency, expense, or volume. Once the team has identified a good candidate problem to solve, it is recommended that objective evaluation criteria be established to address different core concepts. In addition to technical criteria, determining regulatory pathway, intellectual property protection strategy, target cost, business models are factors to be considered prior to selecting a concept for development.

One must understand the opportunity for innovation in the chosen space. This involves the potential market size and how the problem is currently addressed. Developing a medical device is a capital intensive proposition that requires a comparable potential for sales to justify making the

large up-front investment. The team should research the prevalence of the disease state or system problem that the device will address, estimate how many of those patients require surgical intervention to get an estimate of the size of the customer base, and make an estimate of how much the technology would cost to a customer (understand that these costs are borne by insurance payers or health care systems/hospitals). At this stage, customer discovery is key (please refer to the chapter on “Conducting Insightful Market Research”). Obtaining this information will allow the team to make a rough estimate of the potential market size for the device. It is important to have alignment between “who pays” and “who benefits” for a particular device. Without this alignment, market penetration can be very difficult. As an example, if a new device reduces length of postoperative hospital stay in a bundled reimbursement model, it would be best to create a business strategy where the hospital pays for the device. An insurance provider would not have any financial incentive to pay a premium for the device, since their cost structure would remain unchanged. As a rule of thumb, a market size that will support the cost of development and clinical trials for a premarket approval (PMA) device is at least \$500 million (Durfee and Iaizzo). With a better understanding of the size of the customer base, the cost of goods for the technology, and the development of the business model, the market size estimates can be refined. After assessing the potential market size for the device, it is important to assess the competition. One should have a thorough understanding of any competitive solutions currently available or under development that address the same problem the startup is aiming to solve with their device.

The next step in the pre-development stage is to determine customer needs (see the chapter on “Identifying Unmet Needs: Problems that Need Solutions”). This may involve interviewing potential customers and observing the target users in their environment, a process known as contextual inquiry (Medina et al.). It can be useful to observe surgeons using the techniques and devices that are currently available to better understand how the device should function to fit the surgeon’s and the patient’s needs (see the chapter on “Human-Centered Design: Understanding Customers’ Needs through Discovery and Interviewing”). It is important to note, however, that user input should not be taken at face value, as users often have a current solution bias. Understanding how a user measures success is an essential step that can save design time and prototyping costs that would otherwise be wasted if the team designs a product that does not provide a meaningful benefit.

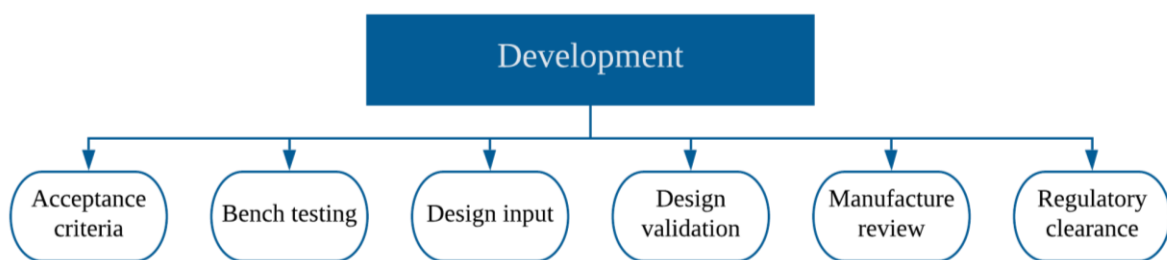
Each user need should be translated into a design specification that can be verified and validated in the development phase. At this point, divergent concepts can be generated and evaluated against the respective criteria outlined above. This is an iterative process that involves the best features of each concept and then creating new ones. For example, the team could generate concept A and concept B. Instead of doing a comparison between the two and selecting the best option, the best features of concept A are combined with the best features of concept B to create concept C. At any point during this iterative process “bread board” prototypes can be created to facilitate quality feedback from key opinion leaders and stakeholders.

The regulatory pathway and intellectual property (IP) protection strategy (see chapters 20 & 21) can be evaluated with increased confidence with a concept and should be part of concept selection process. A concept gives something for respective experts something meaningful to evaluate and perform predicate and prior art searches. These factors will help determine the go-to-market strategy. Another consideration is that the business model will largely be tied to the reimbursement structure for the procedure the team is targeting with the device. These are important considerations for achieving product market fit.

Early on in development, it is a good idea to discuss the technology solution and preliminary go-to-market plan with an FDA regulatory expert and a Centers for Medicare and Medicaid Services (CMS) reimbursement expert (see the chapters on “Strategic planning and costs of FDA Device regulation” and “Reimbursement Strategies and CPT Codes for Device Development”). The FDA expert can help point the team toward the fastest and least expensive pathway to approval—for instance, if there is a choice between a technology that can be considered reasonably similar to a predicate device (510K), vs. an entirely new technology that would require a New Device Application (lengthy and more expensive). In addition, the claims of the new device can be modified so that FDA classification can be lower (exempt or class I) for a device that is a treatment aid, vs. class II or III for a device that is claimed to be used for diagnostic or therapeutic purposes directly. The CMS expert can tell the team how the government would reimburse the provider or healthcare system for the use of the new device or procedure. This information is essential for the go-to-market strategy, as it determines how the device is purchased—if it is disposable, reusable, pay per use, or if the device should be purchased up front. Also, if a device/procedure is brand new, then the startup company will have to petition the CMS to develop a billing code for it, and eventually assign a reimbursement value to that code (Pietzsch et al.). This is a long pathway and can make or break a new technology. This information can be used to create a strategic roadmap that includes calculating the return on investment (ROI), internal rate of return (IRR), or break-even analysis for established companies and “time to liquidity” for startups.

Development

Figure 3. Breakdown of the Development Phase.



At the conclusion of the pre-development phase a concept should be selected that has enough detail that can accurately define the design inputs and business case for development. This includes performing a prior art search and filing provisional patents, determining the regulatory pathway, having a clear business model, and required resources. The development phase is often led by a project manager or engineer for outward facing member of the development team and is the steward of the development process. Development teams are highly cross-functional and in many cases include personnel from different organizations.

During the pre-development phase, the prototypes are typically referred to as bread board prototypes. These are prototypes are usually produced using off-the-shelf or 3D printed parts to gather qualitative feedback from key opinion leaders. They may or may not be functional, and give a “looks like, feels like” estimation of the final device. Prototypes made during the development phase are constructed for a specific test that usually has a quantitative or comparative result. Consider an expandable vertebral body replacement implant as an illustrative example. A “bread-board prototype” could be different sizes and configurations of the implant that are 3D printed for surgeons to provide feedback on the “fit” to their patient population. These bread-boarded prototypes may not be able to expand or collapse, but it will allow surgeons comment on how much expandability is required. A prototypes in the development phase could have different expansion mechanisms and would undergo testing to determine the optimal solution for this device based on the design inputs. It is considered a best practice and required accredited design controls to have an approved test protocol prior to testing. The testing protocol may include descriptions of test equipment, rationale for test subjects, test procedure, manufacturing information, and clearly stated acceptance criteria. It is especially important to define the acceptance criteria early, even prior to designing prototypes. It can help developers design products to meet functional targets, and it provides an objective framework to evaluate different ideas and make decisions.

Design verification and validation, often referred to as V&V, is a required part of the development process for medical device according FDA and ISO design controls. Verification is proof that the device was designed correctly. Do the design outputs meet the design inputs? Examples of verification activities include reviewing engineering drawings reviews and test reports. Validation is the process that address the question “is this the right design” based on the user needs and intended uses. Examples of validation activities include cadaveric evaluation with surgeons. Validation occurs after the product has been designed and fabricated, but it does reflect if you properly captured the user needs. The objective of the V&V process is to demonstrate that the final design meets its original intention. This topic is covered in the FDA’s *Design Control Guidance for Medical Device Manufacturers*.

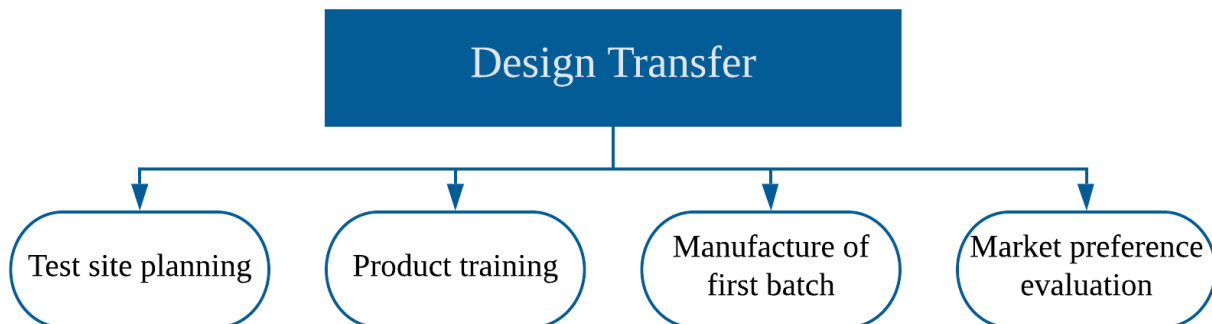
Throughout the process of prototyping and bench testing of different designs, there should be communication with manufacturing experts to ensure that the feasibility of manufacturing is taken into account. Often, manufacturing engineers can advise on where changes can be made to the design

to make manufacturing simpler, cheaper, and more reliable without compromising the design intent. Prior to fabricating a new prototype, a manufacturing review should occur to evaluate the feasibility of manufacturing that design at scale.

Once all ideas have been screened for feasibility, the best have been evaluated through testing, manufacturing review, the verification and validation process, and an optimal design has been chosen, the development team should have a final design and can begin design transfer. At this stage, it is important to begin the formal process of obtaining FDA clearance or approval for the use of the device in human subjects. The regulatory pathway depends on the go-to-market strategy and the characteristics of the device. For example, a 510(k) can be obtained if there are already clear predicate devices approved and on the market. In an academic setting, often initial clinical safety data can be collected by obtaining institutional review board (IRB) approval with or without an Investigational Device Exemption (IDE) from the FDA. IRB staff can often provide guidance as to what qualifies as a “non-significant” risk device that may not require FDA approval for use in patients (see the chapter “FDA Device Regulation: 510(k), PMA”).

Design Transfer

Figure 4. Breakdown of the Design Transfer Phase.



Design transfer is usually the last phase of the surgical device development process. It is a set of procedures that ensure that the device design is correctly translated into production specifications. Detailed guidance on this topic is provided in *ISO 13485 section 4.2.3(c)* and FDA’s *Design Control Guidance for Medical Device Manufacturers*. The production specifications are usually in the form of engineering drawings (part, assembly, functional inspection). The level of detail is related to the complexity of the device and the relationship between the product developers and manufacturers. In many cases, the manufacture of the first batch will be limited size completed with greater inspection fidelity to make sure the product is being manufactured as intended. In some cases, the first batch may be used for testing to ensure the production devices are performing as required.

Prior to general market availability, new surgical devices may go through a Market Preference Evaluation (MPE). This analogous to a beta launch in the tech industry. The purpose of the MPE

is to validate key business questions and stress test the supply chain in a controlled manner. Key business questions can include the quality/level of product training required, confirm size ranges, packaging appropriateness with hospital procedures, pricing, etc. It is important that the same level of objectiveness is applied to evaluating these business questions as was used during the development process. It is recommended involving surgeons not part of the development team to be part of the MPE.

During the initial clinical testing stage, close attention should be paid to user feedback (Sawyer et al.). Users may have suggestions for slight modifications to the design that could greatly improve its functionality and usability, or they can point out flaws in the design that the team can address prior to a full scale launch.

Post-Market Activities

Figure 5. Breakdown of Post Market Activities Phase.



If initial clinical tests are successful and the results of the market preference evaluation indicate that commercialization of the surgical device should move forward, the startup company or their commercial partners can launch the product and enter the post-market activities phase (Figure 5). During this phase of development, operations must be scaled up to meet manufacturing and sales quotas. The product must be maintained, improved wherever possible (if, for example, a slightly more efficient method of manufacturing on large scales can be made by a slight design change), and monitored for any adverse events reported.

During this phase, product refresh or extension strategies should also be explored. Marketing and advertising strategies should be developed to ensure the product is reaching as much of the customer base as possible. The company should look for ways to improve the cost structure to allow price reductions for the product. For example, perhaps a different manufacturing company can make the device more inexpensively or perhaps a simpler manufacturing technique can be used. The team should look to add value to the product and bring the device to new markets.

Early on in this phase, or even before, the team should know how competing products are distributed. Are there synergistic potential partners out there that would be willing to add this new product to their sales portfolio? Alternatively, can the startup company build and field a sales team and set up a distribution network to compete? Knowing the answer to these important questions early on can help with budget projections as well as investment pitches.

Between each of the above stages—pre-market, development, design transfer, and post market activities—it is a good idea to reevaluate progress and make go, stop, or pivot decisions. If steady progress is being made and all is moving as expected, leadership can make a “go” decision and continue moving forward. If problems are continually plaguing development and designs are not working as hoped, it is important for a development team to have the discipline to know when to stop product development and abandon a project. If instead the team finds that it might be more feasible or profitable to take the technology in a different direction than what was originally envisioned, the team should be ready to “pivot” and change the course of product development.

Obtaining Expert Counsel

At university centers, there are often a broad range of resources available where one can obtain expert counsel during the process of surgical device development (Toner and Tompkins). One extremely valuable resource can be institutes or centers focused on medical device innovation, which exist at many universities. For example, at the University of Pennsylvania, there is the Penn Medicine Center for Health Care Innovation, which sponsors a Medical Device Accelerator program. In addition, the FDA has a Pediatric Device Consortia Grant Program, which is available at several academic centers to support pediatric medical device work. Such programs may provide resources for all phases of medical device development, from need identification through idea vetting to business planning and implementation. They may also offer access to project management resources and consulting, grants or early-stage funding for testing and prototype development, or networking events to bring innovators together and provide education on the device development process. Individual university classes may also be interested in taking on a potential project as a learning experience for students, although in this case there may be IP ramifications that are worth exploring with the university’s technology transfer office related to student ownership of IP. In addition to university resources, health systems or medical schools often offer similar resources to aid medical device innovation. There also exist companies outside of academia that can help with the design process for a fee.

For support with intellectual property, company formation, team recruitment, business development and operations, and capital acquisition, the university’s technology transfer office is an excellent resource. Some may include a venture fund or support arm that provides a range of products and services to incubate the development of early-stage technology-based businesses. These may employ student teams from an affiliated business school to perform market analysis

and begin developing business strategies and to provide support and advising for grant applications, such as Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) funding.

In addition, the Coulter Foundation has endowed 16 universities with Translational Research Program funding. These programs provide pilot funding and access to experts and investors and are intended to foster the rapid development of new technologies to aid healthcare by joining physicians and engineers for translational projects (Coulter).

Conclusion

Surgical device innovation is crucial for advancing healthcare and improving patient outcomes. Academic institutions play a crucial role in the development of new surgical devices. Bringing a new device from initial concept to final product is a disciplined process that involve assumption testing, design iterations, and decisions. However, having an objective framework for decision making increases the likelihood of developing a device that addresses the initial user needs with market viability. Choosing the right team of collaborators with a wide range of skills is essential, and seeking counsel and making use of university resources will also improve chances of success.

Resources

1. Medical Device Innovation Handbook
 - a. This handbook, written by William K. Durfee and Paul A. Iaizzo at the Medical Devices Center at the University of Minnesota, provides a thorough overview of the medical device product development process, from initial ideation to pitching the idea and obtaining funding sources.
 - b. Handbook available here: http://www.iem.umn.edu/assets/Medical_Device_Innovation_Handbook.pdf.
2. How to Commercialize Your Novel Medical or Surgical Device
 - a. This article, written by Tomer Davidov, MD, in 2013 for the Association for Academic Surgery, reviews the steps involved in developing and commercializing novel surgical devices.
 - b. Article available here: <http://www.aasurg.org/blog/commercialize-novel-medical-surgical-device/>.
3. Medical Device Development: From Prototype to Regulatory Approval (Kaplan et al.)
 - a. A helpful review that discusses how new interventional devices are developed and regulated, as well as “sticking-points” that delay the process.
 - b. Article available here: <https://doi.org/10.1161/01.CIR.0000134695.65733.64>.
4. IDEAL Framework for Surgical Innovation 1: The Idea and Development Stages (McCulloch et al.)

- a. Provides an overview of the IDEAL framework for the evaluation of surgical innovations.
- b. Article available here:
<https://doi.org/10.1136/BMJ.F3012>.

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