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Measuring Innovation of Medical Products

We conducted a targeted literature review to identify measures of innovation in the medical product ecosystem, evaluate associated trends, and assess their strengths and limitations.

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KEY POINTS

- Increasing innovation in medical products is a policy priority. A first step to understanding changes in the level of innovation is to determine how to measure the baseline of innovation.
- Existing research employs a variety of measurement methods–scientific, therapeutic, and economic measures–to study trends in medical product (e.g., drugs, biologics, devices) innovation.
- Scientific innovation measures were the most commonly used and included counts of new molecule or device approvals. Therapeutic innovation measures included the assessment of clinical value. Economic innovation measures included research and development productivity.
- Each innovation measure has its strengths and limitations in how well it captures the breadth and depth of biomedical innovation. This makes it difficult to use a single measure to definitively determine both the current level and changes in the level of medical product innovation.
- A novel measurement method that more fully captures the clinical benefit of innovations needs to be created to fully assess the robustness of the medical product development ecosystem and the effects of new policies on innovation.

BACKGROUND

Creating innovative medical products is a central to public health. Innovation in medical products can lead to substantial health improvements for patients: new treatments and choices for diseases or improved treatment options with greater efficacy, fewer side effects, or increased safety.

It is easy to see the value placed on innovation by policymakers by the number of legislative actions taken to promote it over the last forty years. Examples include: (1) the Orphan Drug designation program, which was created by Congress in 1983 to provide financial incentives for the development of drugs for rare diseases; (2) the Priority Review designation program, which was created in 1992 to reduce US Food and Drug Administration (FDA) review times for therapies that provide a significant improvement to patients with serious diseases; and, (3) the Breakthrough Therapy designation program, which was created in 2012 to speed patient access to promising new therapies by reducing development times.

The ability to measure medical product innovation is a critical analytic foundation to assess the baseline effects of these, and other, legislative actions. This ability also allows policymakers to better identify gaps in research

and treatment options, such as where the most significant unmet needs lie, as well as to assess the overall health of the medical product development ecosystem. It is not possible to fully understand the effects these programs are having on stimulating innovative product development, as well as gaps in, and the health of, the system if we are not able to accurately and consistently measure medical product innovation.

However, a unified measure of medical product innovation remains elusive. There are two main impediments to measurement: (1) heterogeneous value in different types of innovation, and (2) data availability. To illustrate these challenges, we can take as an example a common measure of innovation: new molecular entities (NMEs). NMEs are small molecule drugs or biologics that have not previously been approved in the US.[1]

NMEs are frequently used as a measure of medical product innovation because there is high data availability. FDA's Center for Drug Evaluation and Research (CDER), which regulates the approval of small molecule drugs and therapeutic biologics, publishes an annual list of NME approvals as well as a dataset, updated yearly, of all NMEs (and associated regulatory characteristics) from 1985-present.[2] However, using NMEs as a measure of innovation is limited because there is a high level of heterogeneity in the innovative value of each NME. For example, some NMEs represent true breakthroughs in the standard of care for a disease, while others provide only marginal benefits to patients; their common element is the newness of the molecule in the US regulatory context, not the therapeutic value of the product. This heterogeneity limits the measure's ability to uniformly measure innovativeness across products and time.

In this issue brief, we perform an environmental scan of the literature to identify the ways that medical product innovation has been measured and the innovation trends associated with each method. We then build on the literature by discussing the strengths and limitations of each measure. This work provides a foundation for determining whether current measures of medical product innovation are adequate to measure innovation, or whether advances, such as the creation of a novel measure, are needed.

METHODS

To compile a comprehensive list of measures of medical product innovation (for both drugs and devices) we began by reviewing literature from a targeted review of both peer-reviewed and grey literature using the following keywords: "innovation", "US market", "pharmaceutical", "drug", "medical device", "innovation", "measure", "patent", "approval", and "trend."

We searched a range of databases, including PubMed and Google Scholar, for the peer reviewed literature. For the search of the grey literature, we utilized Google and LexisNexis. We limited our initial search to 2013 to 2024 and those relating to the U.S. market. We identified additional supplemental articles prior to 2013 using a "snowball" approach based on the initial targeted search. This search strategy yielded 23 relevant literature sources after reviewing abstracts and excluding literature sources that did not include innovation measures for medical products.

From these reports, we identified categories of innovation measures that researchers and policymakers have used or can use to describe medical product innovation. We found three categories or themes of innovation measures that described different aspects of medical product innovation: scientific, therapeutic, and economic (Figure 1). Scientific referred to measures of innovation used to describe technological advances. Therapeutic measures ascertained the clinical benefit of the medical product over existing therapies. Economic measures of innovation, primarily financial metrics, shed light on the extent to which investment dollars or resources led to more products or increased sales.

RESULTS

In this section we present in more detail the scientific, therapeutic, and economic measures of innovation we found, and the trends in innovation that researchers have drawn from them.

Scientific Measures of Innovation

Within the scientific category, we found three types of innovation measures: molecular structure, device design, and patents (Table A1). Measures based on molecular structure are specific to drugs and biologics (henceforth "drugs"), while those based on device design are unique to medical devices. Patents, which describe technological advancements, are applicable to both products. In this section, we first describe the groups and measures of molecular structure (drugs), device design (medical devices), and patents (both), and conclude with the innovation trends related to these measures.

Molecular Structure (Drugs)

There are two existing measures of molecular structure: counts of NMEs and analysis of chemical structure. Counts of NMEs, while an assessment of molecular structure, is also a regulatory measure. As described in the introduction, an NME is defined by the FDA as "an active ingredient that contains no active moiety that has been previously approved".[1] NME approval information is also published on FDA's website allowing for easy access to detailed drug information and longitudinal observation of trends. The standard definition and high level of data availability makes counts of NME the most studied measure of pharmaceutical innovation in our review.

Both highly innovative drugs and addition-to-class drug products (i.e., those that work similar to an existing drug on the market and treat the same condition) are included in counts of NME.[3] As a result, this measure is a broad definition of innovation that includes both radical and incremental improvements in clinical value. In an attempt to mitigate this heterogeneity, some research has examined a subset of NMEs, first-in-class drugs, which are those containing a novel mechanism of action that differs from existing drugs on the market for a given disease.[3] This measure is thought to be more uniform when assessing innovation, as these products have the same, higher, level of scientific innovation, however they retain the same limitation as NMEs as a whole, which is that they do not distinguish the clinical value of the product. FDA also publishes a list of first-in-class NMEs, providing researchers with access to this information.

Researchers have also analyzed the chemical makeup of drugs to assess pharmaceutical innovation (e.g., compound similarity or compound-to-target protein). One approach is by comparing a drug's chemical structure to existing ones – greater differences suggest more technological innovation.[4] Another method tracks the number of new biological areas that are targeted by a group of drugs. If there are fewer target areas, it may signal a decline in innovation.[5] To perform this innovation analysis, researchers review chemical databases and scientific publications to identify a drug's structure and its intended biological target.[4, 5]

Evaluating innovation using molecular structure is possible due to high data availability (published on the FDA website or public databases) and standard definitions that enable comparison longitudinally. While all these measures assess technological advancements in pharmaceuticals, they do not consider clinical benefit or affordability, which drive utilization and impact population health.

Device Design (Medical Devices)

The approval pathways of medical devices, 510(k) clearances and premarket approvals (PMAs), have been used as measures of scientific innovation.[6] Similar to NMEs, the FDA has a standard definition for devices with

510(k) clearance and PMA approvals. Devices with 510(k) clearance are substantially equivalent to another device already on the market (predicate device exists). [7] PMAs are given to products that support or sustain human life and are not substantially equivalent to existing devices, and generally require clinical trial data to support approvals.[7, 8] The FDA publishes data on device clearances and approvals, providing researchers with access to details about the devices and the ability to track changes over time.

As devices with 510(k) clearances are substantially equivalent to an existing product, they are an addition-to-class and measure incremental improvement rather than radical innovation.[7] To differentiate between radical and incremental innovation, researchers have also examined the number of citation-weighted 510(k) clearances.[7] Researchers can determine the scientific value of the original medical device referenced by the 510(k) clearances by assessing the number of these products that use the original as the predicate device.[7]

Studies have categorized devices with PMA approvals as more innovative than those with 510(k) clearances.[7] Therefore, some researchers used PMA approvals as a method to identify radical innovation. PMA approved products involve new designs (without a predicate device) and support or sustain human life (class III – high risk). [7, 8] These requirements suggest that PMA approved devices offer more clinical benefit than other types of device approvals. A limitation with using 510(k) clearances and PMAs as measures of innovation is some devices are exempt from these requirements altogether based on their low risk level.[9] Therefore, not all important device innovation may be captured with this measure.

Similar to molecular structure measures for pharmaceuticals, measures using counts of 510(k) clearances and PMA approvals are feasible because of standard definitions and data availability from the FDA. Though the type of regulatory designation or approval provides some distinction of radical or incremental innovation, via both technical and clinical perspectives, a full measurement of innovation is not possible due to confounding with device-related risk.

Patents (Drugs and Medical Devices)

Researchers have also used patents as a measure of scientific innovation. The United States Patent and Trademark Office (USPTO) grants patents for new designs or new utility (e.g., manufacturing process).[10] Therefore, patents are applicable to both pharmaceuticals and medical devices. Details of filed patents are also publicly available and searchable on the USPTO website, enabling researchers to compare patent trends.[10] Patent measures include simple count of patents, citation-weighted counts, and market value of a patent (e.g., how much the patent impacts the company's stock or valuation).[7]

Simple counts of patents is a broad measure which encompasses both incremental and radical innovation. [7, 11, 12] Citation-weighted counts further delineates incremental and radical inventions by incorporating how useful or novel the patent is and the extent to which each patent leads to other scientific advances.[7, 11, 12] However, this method requires creating a weighting scale and estimating clinical benefit of a scientific measure, which may lead to substantial subjectivity.[7] Other studies have examined the market value of patents to determine whether a patent is competitive or meets a market need.[7, 13] One way to assess market value is to evaluate a company's change in stock price or company valuation after the issuance of a patent.[7]

However, there are limitations to using patents as an innovation measure. Patents are used primarily as a business asset and not a signal for innovation; for example, companies are not required to file patents or may file multiple patents for the same product. Additionally, patents do not indicate product approval, marketing, or clinical value, therefore, they do not consider product utilization, an important proxy for the innovative impact on patient care.

Innovation Trends Using Scientific Measures

Research examining scientific measures of innovation are the most frequently studied in the literature due to high data availability. However, as a group, they offer no unified indication of whether innovation is improving, remaining constant, or declining over time. For example, Schnittker and Karandinos (2010), using counts of NMEs, showed overall innovation is increasing, while Lanthier et al.'s (2013) first-in-class approvals analysis concluded a constant level of innovation, and Southan et al.'s (2013) study conveyed a decline using compound structure analysis.[3, 5, 15]

Therapeutic Measures of Innovation

Therapeutic measures of innovation in our literature review evaluated clinical benefit primarily using either FDA's expedited programs as a proxy or through direct measurement of therapeutic value (Table A 2). These measures are also applicable to both pharmaceuticals and medical devices. Other indicators we found that directly measure therapeutic value included: assessing clinical outcomes, patient convenience, expansion in patient population, and fulfilling unmet patient needs. These indicators may also be aggregated together through a composite benefit assessment that compares the new product to existing therapies, although this is more frequently used outside of the U.S. context. In this section, we discuss measures related to expedited regulatory programs, therapeutic value, and conclude on the innovation trends from these measures.

Expedited Regulatory Programs

In measuring therapeutic innovation, researchers have used FDA data on approvals through expedited programs as a method to identify medical products that offer a significant clinical benefit. For pharmaceuticals, FDA's expedited programs include priority review, accelerated approval, fast track, and breakthrough designation.[16] Researchers have also used approvals granted via these programs to differentiate between novel innovation and incremental improvements (e.g., products approved with versus without expedited programs).

To be eligible for any of FDA's expedited programs, the drug must be intended to "address unmet medical need in the treatment of a serious or life-threatening condition".[17] Priority review shortens FDA's timeline from ten months to six months.[16] Accelerated approval allows pharmaceuticals to be approved using a surrogate endpoint.[16] Fast track and breakthrough designation are intended to expediate drug development and review, but fast track designation can be given using non-clinical information while breakthrough designation requires clinical data.[16] Pharmaceutical products may be eligible for multiple expedited programs.

Though research articles in this analysis did not study medical devices using expedited programs, it would be possible to use the same measurement method. Devices have two such programs, the breakthrough program and the safer technologies program (STeP).[18] The breakthrough program is for devices indicated for "treatment or diagnosis of life-threatening or irreversibly debilitating diseases or condition".[18] STeP is for devices "that target an underlying disease or condition" that has a lower mortality or morbidity risk than the conditions or diseases eligible for breakthrough device consideration. Both programs provide an expediated review for eligible devices.[18]

While the expedited regulatory program measure assesses clinical benefit and the data are publicly available on the FDA website, it does not consider utilization. Clinical benefit is also based on presumed efficacy, and thus may not be perfectly correlated with the benefit once the product is used by patients (e.g., effectiveness).

Therapeutic Value

Although less prominent than research using scientific measures of innovation, research is increasingly incorporating therapeutic measurements to evaluate the clinical benefit of medical products. Some countries, such as Germany, use direct therapeutic value (benefit assessments) for reimbursement evaluation. Studies have explored the therapeutic value of medical products in countries such as Canada, France, Germany, and Italy using these assessments (Table A 4).[14, 19, 20] Despite variations in assessment methods, these measures aim to determine whether a new medical product offers advantages over existing treatments and can influence reimbursement rates in these countries.[14, 19, 20] Using direct therapeutic value or benefit assessments as a measure evaluates the actual patient benefit but is resource-intensive, requiring comparable clinical data on both new and existing products. Challenges such as data availability and evolving medical standards also make benefit assessments difficult to compare across time and therapeutic area.

Innovation Trend Using Therapeutic Measures

Measuring innovation using clinical benefit sheds light on the extent to which new drugs and medical devices advance treatment options. However, when using therapeutic measures of innovation, there remains no definitive indication on direction or extent of innovation over time. For example, Hwang et al. (2020) concluded that while drugs approved through an expedited program were more likely to have high therapeutic value, majority of new drug approvals had low value.[21] Wills and Lupus' (2020) research combining scientific (compound structure analysis) and therapeutic measures (breakthrough therapy) found new compound structures were 2.6 times more likely to offer a clinical benefit over existing structures.[22] These studies suggest that merely counting the number of new approvals fails to capture how much new medical products benefit patients or offer novel treatment options, highlighting the need to include therapeutic measures when describing the state of innovation.[14, 21, 22]

Economic Measures of Innovation

Economic measures of innovation evaluate financial metrics and resource allocation, and include: if innovations drive increased sales, how investments translate into drug and device approvals, and cost-effectiveness of innovations (Table A 3). The measures we found in the literature included: sales, order of market entry, R&D productivity, and cost-effective analyses. Sales is revenue generated by the drug. Order of market entry identifies when products began sales, relative to other products in a defined market space.[15] R&D productivity evaluates outputs (e.g., sales, NME approvals) relative to inputs (e.g., investments).[23, 24] Cost-effective analysis studies calculate the benefit and costs of a treatment over existing options to compare therapeutic value and costs.[25] In this section, we first discuss each measure and conclude with the innovation trends from these measures.

Sales

Sales data, though not always publicly available, provide an easy comparison of how an innovation has affected healthcare expenditures. Deshpande et al. (2010) and Roberts (1999) discussed use of sales revenue from new medical products as a measurement method to determine how much of the market the product is capturing.[14, 26] In Roberts (1999), innovative drugs were defined as capturing a minimum threshold of 15.6 percent market share, and concluded that using this metric just 14 percent of new drugs would be considered innovative.[14, 27]

Order of Market Entry

The order of market entry is used to rank the level of innovation for medical products.[15] The first product entering the market is considered to have a higher innovative contribution than subsequent entries, making it stronger competition for existing treatments.[15] This enables researchers to distinguish radical from follow-on drug products (incremental improvements). Robberson and Breder (2021) used order of market entry (based on market share) to derive an innovation score with higher scores given to early entry medical products.[15] Their research showed an overall increase in innovation since the 1970s.[15] This method can easily distinguish between novel and follow-on products but does not assess therapeutic value.

R&D Productivity

To evaluate R&D productivity, researchers examined the number of NMEs approved or sales generated by the amount of R&D investment provided.[24] Several authors using this method concluded that R&D productivity has declined over time.[23, 24, 28] For example, both Pammolli et al. (2011), who examined drug development from 1990-2007, and Schuhmacher et al. (2021) from 1999 – 2018, found a decline in R&D productivity driven by an increase in investment expenditures.[24, 28] Schuhmacher et al.'s 2023 study also found companies shifted towards merger and acquisitions (M&A) as a response to declining productivity.[23] The R&D productivity measure evaluates efficiency and distribution of resources but does not directly evaluate of fully incorporate utilization or therapeutic value.

Cost-Effectiveness Analysis

Researchers have also used cost-effectiveness analysis (CEA) to assess the clinical benefit of new medical products. Dunn et al. (2023) used the number of CEA's published as a proxy for innovation and but did not make any conclusions as to the state of innovation.[29] Nelson et al.'s (2009) systematic review of published CEAs revealed that most assessments found only incrementally cost-effective innovations, meaning these innovations achieved only marginally better health outcomes for their cost.[30] Both studies suggested that innovation led to improved treatments but also to increased spending. This measure assesses both therapeutic value and costs, but it is resource intensive to create as data needed to determine benefit assessment may not be readily attainable.

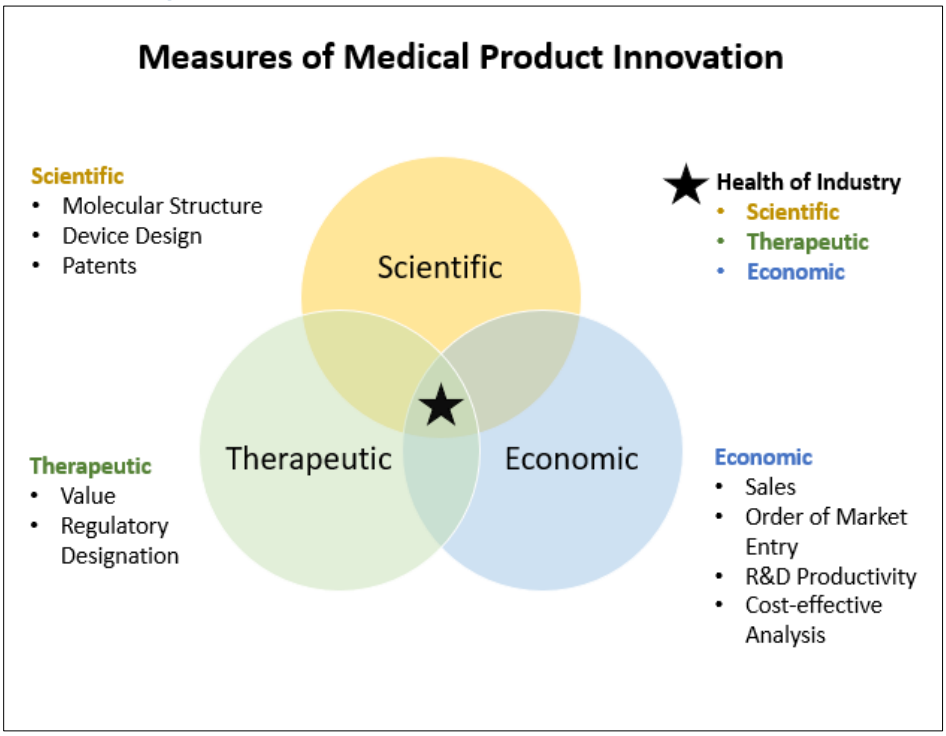
Trends in Economic Measures

Overall, research examining economic measures results in varying conclusions about innovation. Sales data and R&D productivity show only a limited number of products are innovative. Order of market entry research finds innovation has been increasing over time, while cost-effectiveness analysis suggests innovation is leading to increased expenditures. These differences in conclusions may be related to the larger R&D investments required to bring new products to market, with industry focusing on higher-risk target areas (e.g., diseases that are more difficult to treat). While economic measures are useful in assessing resource allocation and some include clinical benefit evaluation, these measures are difficult to compare across diseases due to varying levels of R&D risk. Metrics such as sales and cost-effective analysis are dependent on the researcher's chosen threshold for novel or incremental innovation, while cost-effectiveness analysis is more resource-intensive due to issues with data availability on therapeutic value.

DISCUSSION

Current literature contains many approaches to measuring innovation, yet no single measure captures all aspects of innovation (Figure 1) and each has strengths and limitations as a measure (Table 1).

Figure 1. Measures of Innovation from Literature Search



Scientific measures like molecular structure, device design, and patents have easily accessible data on public databases (FDA, USPTO, etc.) with standard definitions that enable researchers to observe technological changes over time. However, these measures have a number of limitations such as all products are assumed equally clinically innovative, regulatory approvals do not capture all types of medical product innovation (e.g., new indication approvals or low-risk device innovation), and firms may withhold filing patents to retain confidentiality.

For therapeutic measures of innovation, the largest benefit is that it directly reflects improvements to patients' health resulting from new drugs or medical devices entering the market. However, many of these measures are limited due to difficulty of aggregating or determining clinical benefit. For example, measures that count the number of expedited reviews captures the anticipated therapeutic value at the time of application, rather than the actual therapeutic value once the product enters the market.

While economic measures can be an important measure of medical product innovation because they assess the efficiency of resource allocation, such as investment dollars. However, the measures are difficult to compare across disease types and may not include precise measurements of clinical benefit. There are also larger trends in the medical product development ecosystems that can bias longitudinal comparisons of these measures. For example, as development shifts towards more difficult-to-treat areas, increased R&D investment biases innovation trends downward, despite potentially high therapeutic value.

Table 1: Strengths and Limitations of Measures for Biomedical Product Innovation

	Strengths	Limitations
Scientific Measures of Innovation	• Common definition • Captures technological novelty • Comparable across time points • Data is accessible	• Assumes all approved products are innovative • Regulatory approvals (510(k) and PMA) do not capture all medical device innovation • Firms may decide against filing a patent • Key patents may be missing from databases • More difficult to assess market-value of patent • Multiple patents may apply to product • Time lag between patent grant and citation • Value of innovation not captured
Therapeutic Measures of Innovation	**Strengths**	**Limitations**
	• Identifies innovation intended to treat serious health condition and unmet patient needs • Incorporates clinical benefit to patients	• Greater safety issues after approval are associated with certain expedited approval pathways • Lack of data for assessment • Regulatory designation assumes a therapeutic value • Resource-intensive to build robust measure • Standard of medicine changes over time
Economic Measures of Innovation	**Strengths**	**Limitations**
	• Assesses efficiency of resource allocation • Describes product utilization • Some measures combine therapeutic value and cost	• Difficult to compare across diseases • Level of innovation depends on threshold chosen for comparison • More difficult to treat health conditions typically require more R&D investment • Patients may opt for lower cost products which biases sales data • Resource-intensive to build robust measure

The measures of medical product innovation we identified also align with existing meta-analysis and systematic reviews (Table A4). Five of the meta-analysis and systemic reviews we found examined all three categories (scientific, therapeutic, and economic), while two examined only therapeutic or therapeutic and economic. The reviews had some degree of overlap in their study period but, like our analysis, there was no consensus on trends in innovation. Additionally, a majority of papers evaluated innovation broadly with some authors distinguishing between novel and incremental improvements. Only Gressler, *et al*. (2023) created a compositive measure, described as a "qualitative framework to identify and prioritize opportunities" in medical product development that included metrics on biomedical innovation (scientific), public health burden (therapeutic), and health care cost (economic).[34]

Our analysis also identified gaps in the literature. Though the scientific, therapeutic, and economic measures identified above can examine changes in innovation for both drug products and medical devices, more research is focused on drug products. For example, the *de novo* pathway is a relevant medical device classification that did not appear in our literature search. The FDA grants this classification to novel devices that lack a predicate device but are lower risk than class III, meaning they do not satisfy 510(k) requirements or PMA approva.[33] However, *de novo* classifications could be interpreted as significant innovations. The different legislative and regulatory ecosystems of pharmaceuticals and medical devices, as well as the distinct markets for them, warrant additional research on medical devices to fully understand their innovation landscape.

The results of our study come to a central conclusion: the current methods used to measure innovation are inadequate. They fail to uniformly measure clinical benefit, which is the most critical aspect of innovation to the healthcare system and patients. Without a uniform measure of the central aspect of innovation, a baseline level of innovation cannot be precisely obtained, and an understanding of trends in, and policy impacts on, innovation cannot be satisfactorily determined. This measure should be able to both distinguish differences in clinical benefits of new products and also capture the value of incremental innovations (such as new indication approvals). While creating a new measurement of innovation using clinical benefit as the central data point is difficult due to data limitations and differences across diseases, researchers should begin to explore options for this novel measure because determining a baseline for innovation is critically important.

LIMITATIONS

Our analysis has several limitations. First, search terms may not have captured all relevant literature and may miss additional measures of innovation. Second, we limited our search to studies focused on the U.S. Third, the measures we identified do not capture all medical product innovation, such as devices exempt from 510(k) clearance and PMA approval. Lastly, the articles in this paper studied only pharmaceutical, medical devices, or both. Our research did not evaluate innovation in diagnostics or areas that help development of medical products such as artificial intelligence or drug discovery techniques.

CONCLUSION

The existing literature employs various methods to study medical product innovation, including a host of scientific, therapeutic, and economic measures. Either of the measures we describe have strengths and limitations in their ability to fully describe medical product innovation. However, no measure adequately describes the clinical benefits of innovations (both new and incremental), and we therefore conclude that a novel measure should be created. The creation of this novel measure will enable researchers to more accurately examine health of the medical product development ecosystem, gaps in innovation, and the ways in which legislative policies impact medical product development.

APPENDIX A: LIST OF SCIENTIFIC, THERAPEUTIC, AND ECONOMIC MEASURES

Table A 1: Research Using Scientific Measures to Evaluate Changes in Medical Product Innovation

Product Type	Study Author(s)	Time Period	Method Type	Method	Results	Conclusion on Innovation	Innovation Trend[1]
Drug	Schnittker and Karandinos (2010)[35]	1960-2000	Molecular Structure	• Count of NMEs • Number of priority approvals	NME approvals increased from a low of less than 10 (1968) to greater than 50 (1996) and priority approvals increased from less than 5 (1961) to greater than 15 (1996).	Innovation has increased over time.	↑
Drug	Lanthier et al. (2013)[3]	1987-2011	Molecular Structure	• Count of NMEs (first-in-class, advance-in-class, addition-to-class)	Addition-to-class are driving NME approvals. First-in-class approvals have remained constant.	First-in-class approvals remained constant from 1987 to 2011 with higher proportion of approvals in later years.	↔
Drug	Juliano (2013)[36]	1970-2002	Molecular Structure	• Count of NMEs	In 1970, NME approvals per year were between 10 to 20 and in 2022, between 20 to 30.	No conclusion.	N/A
Drug	Southan et al. (2013)[5]	1991-2010	Molecular Structure	• Analysis of chemical structure (extracted from patents, publications)	Since 2012, output of new compounds had decreased by 35 percent due to mergers and acquisitions (M&A).	Innovation is decreasing due to M&A.	↓
Drug	Kinch and Raffo (2015)[12]	1930-2013	Patents	• Patents	Increase in diversity of patent holders for biologics and NMEs, with later years seeing contributions from pharmaceutical companies, academia, and biotechnology companies.	No conclusion.	N/A
Drug	Krieger et al. (2016)[4]	N/A	Molecular Structure	• Analysis of chemical structure (compound similarity)	New measure proposed to estimate drug novelty.	No conclusion.	N/A
Drug	Attwood et al. (2018)[37]	1983-2017	Molecular structure	• Counts of NMEs	Biologics and orphan drugs represent a greater proportion of newly approved drugs.	Innovation moving towards biologics and orphan drugs.	N/A
Drug	Wills and Lipkus (2020)[22]	1942-2019	Molecular structure	• Analysis of chemical structure	Number of pioneer drugs from 1990 to 2019 increased significantly.	Pharmaceutical innovation has increased.	↑
Drug	Okayama (2024)[38]	2012-2023	Molecular Structure	• Count of NMEs (first-in-class, late entry)	Small and medium sized businesses are involved in both first-in-class and late entry drug approvals.	No conclusion.	N/A

[1] ↑ (arrow up) symbolizes innovation is increasing, ↔ (sideways arrow) symbolizes innovation is constant, and ↓ (down arrow) symbolizes innovation is decreasing.

Product Type	Study Author(s)	Time Period	Method Type	Method	Results	Conclusion on Innovation	Innovation Trend[1]
Drug, Device	Verhoeven et al. (2016)[11]	1980-2011	Patents	• Patents	Method to classify patents into 3 categories: (1) novelty in combining principles and components, (2) novelty in technological origins, and (3) novelty in scientific origins.	Patents that combine all 3 aspects of technological novelty have a significantly higher impact.	N/A
Device	Everhart (2020)[7]	Not listed	Device Design, Patents	• Counts of PMA approval • Counts of 510(k) clearance • Citation-weighted 510(k) clearances • Citation-weighted patents • Market value of patents	Existing measures are broad descriptions of medical device innovation but do not focus on value of patents or product.	No conclusion.	N/A
Device	Xiao (2022)[39]	1996-2016	Device Design, Patents	• Patents • Counts of 510(k) clearances • Counts of PMA approvals	Enforcement of non-competes leads to more exploitative innovations (builds on existing knowledge) than exploratory innovations (new knowledge).	No conclusion.	N/A
Device	LexisNexis Website (2023)[13]	Not listed	Patents	• Patents • Patent quality (competitive impact)	Identified top medical device companies based on patent quality and portfolio size.	No conclusion.	N/A

Table A 2: Research Using Therapeutic Measures to Evaluate Changes in Medical Product Innovation

Product Type	Study Author(s)	Time Period	Method Type	Method	Results	Conclusion on Innovation	Innovation Trend[2]
Drug	Hwang et al. (2020)[21]	2007-2017	Regulatory Designation, Therapeutic Value	• Regulatory designation (FDA and EU) • Therapeutic value	Among 267 new drugs approved, 31 percent had high therapeutic value. Of the drugs approved through an FDA expedited program, 45 percent had high therapeutic value compared to only 13 percent of drugs approved through standard review.	Drugs approved through an expedited program were more likely to have a high therapeutic value, but majority of new drug approvals had low therapeutic value ratings.	N/A
Drug	Wills and Lipkus (2020)[22]	1942-2019	Regulatory Designation	• Regulatory designation (FDA breakthrough)	Number of pioneer drugs from 1990 to 2019 increased significantly.	Pioneer drugs are 2.6 times more likely to have promising therapies (breakthrough designation) than non-pioneer drugs.	N/A
Drug	Stiller et al. (2021)[19]	2011-2016	Therapeutic Value	• Therapeutic value (as defined by Germany's health technology assessment)	Only 30 of 147 drugs identified as radically innovative using proposed method (NMEs with major or considerable value assessment using Germany's health technology assessment) compared to 69 of 147 drugs using previous methods of innovation (NMEs with FDA priority review).	Measures of radical innovation should include therapeutic value assessments.	N/A

[2] ↑ (arrow up) symbolizes innovation is increasing, ↔ (sideways arrow) symbolizes innovation is constant, and ↓ (down arrow) symbolizes innovation is decreasing.

Table A 3: Research Using Economic Measures to Evaluate Changes in Medical Product Innovation

Product Type	Study Author(s)	Time Period	Method Type	Method	Results	Conclusion on Innovation	Innovation Trend[3]
Drugs	Roberts (1999)[27]	1977 – 1993	Sales	• Sales (market share)	Using a cut-off of 15.6% market share to delineate innovative products, only 145 of the 1070 products reviewed were innovative.	Only 14% of products introduced were innovative.	N/A
Drugs	Pammolli et al. (2011)[28]	1990-2007	R&D productivity, Sales	• R&D Productivity (sales per NME, R&D investment per NME)	Decline in R&D productivity due to investment in high-risk areas.	Decline in R&D productivity.	↓
Drug	Robberson and Breder (2021)[15]	1938-2019	Order of market entry	• Order of market entry (based on market share) to calculate innovation score	Innovation score calculated for each therapeutic class, mechanism, and drug target and then compared with number of first-in-class approvals each year.	Innovation varied by category, but total innovation increased.	↑
Drug	Schuhmacher et al. (2021)[24]	1999-2018	R&D productivity	• R&D efficiency of top 14 firms (NME approvals of own or acquired firms, publications)	Leading firms launched 270 of 602 NMEs. R&D investment increased in absolute terms and as a percent of revenues.	Decline in R&D efficiency.	↓
Drugs	Schuhmacher et al. (2023)[23]	2001-2020	R&D productivity	• R&D productivity (investment, R&D spending, total sales, NME approvals)	Increase in R&D spending at compound annual growth rate of 6 percent.	Companies use M&As to compensate for negative R&D productivity.	N/A
Drugs, Device	Nelson et al. (2009)[30]	2002 – 2007	Cost-effective analysis	• CEA studies (identify decremental and incremental cost-effective innovations)	99.6% of published cost-effectiveness analysis showed innovations were incrementally cost-effective.	Most innovations with improved health outcomes also have increase in costs from existing treatments.	N/A
Drug, Device	Dunn et al. (2023)[29]	2000-2017	Cost-effective analysis, Sales	• CEA studies • Healthcare spending from U.S. U.S. Bureau of Economic Analysis Health Care Satellite Account	The number of CEA studies from Tufts Cost-Effectiveness Analysis Registry can explain 18 percent of health care spending growth.	CEAs are better proxy for innovation than patents.	N/A

[3] ↑ (arrow up) symbolizes innovation is increasing, ↔ (sideways arrow) symbolizes innovation is constant, and ↓ (down arrow) symbolizes innovation is decreasing.

Product Type	Study Author(s)	Time Period	Method Type	Method	Results	Conclusion on Innovation	Innovation Trend[3]
Device	Everhart (2020)[7]	Not listed	R&D productivity, Cost-effective analysis	• R&D spending • CEA studies (quality-adjusted life years, incremental cost-effectiveness ratio)	Existing measures are broad descriptions of medical device innovation but do not focus on value, prompting a need to evaluate CEA-based methods.	No conclusion.	N/A

Product Type	Study Author(s)	Time Period	Measurement Method(s)	Method	Results	Conclusion on Innovation	Innovation Trend[4]
Drug	Kesselheim (2013)[14]	1966-2012	Scientific, Therapeutic, Economic Measures	Systematic review to determine how to define and measure innovation	Measures of innovation falls into four buckets: Count of new drug approvals, patents, assessment of therapeutic value, economic outcomes, patients issued	Twenty-one studies used counts of new drug approvals, nine showed favorable trend, 11 not favorable, and one no conclusion. For the 14 studies that used therapeutic value, seven showed not favorable and seven had no conclusion.	N/A
Drug	deSola-Morales (2018)[40]	2010-2016	Therapeutic, Economic Measures	Systematic review to identify innovation definition for new drugs	Ten dimensions of innovation identified: therapeutic benefit, novelty, availability of existing treatment, unmet need, safety, newness, administration, clinical evidence, cost, and other	Therapeutic benefit had the highest number of occurrences in published literature (40), followed by novelty (19), and availability of existing treatments (13).	N/A
Drug	Hofman et al. (2021)[41]	2010-2019	Therapeutic	Literature review to determine definition and assessment of innovation related to health technology assessment	Example Measures: drug therapeutic benefit, reduction in side effects, treatment convenience	Patent counts or NME approvals are no longer acceptable measures of innovation. Innovation analysis should include therapeutic value.	N/A
Drug, Device	Deshpande et al. (2019)[26]	Not listed	Scientific, Therapeutic, Economic Measures	Rapid literature review to assess existing measures for biomedical innovation	Example Measures: Regulatory approvals, impact on policy, impact on clinical practice, impact on health and well-being, patient safety, quality of care and outcomes, equity of access, community engagement, population health improvements, outcomes for companies, economic outcomes, productivity of academic research/private sector	Researchers identified potential measurement methods but did had no conclusion on innovation.	N/A
Drug, Device	Syeed et al. (2022)[42]	Inception of database – 2021	Scientific, Therapeutic, Economic Measures	Systematic review to identify measurements and attributes of innovation in healthcare	Example Measures: novelty, step change, substantial benefit, improvement over existing technology, convenience and/or adherence, uncounted benefits, acceptable cost, added value (alleviating societal or patient burden), therapeutic value	Existing measures to evaluate innovation do not capture the full impact of health and cost.	N/A
Device	Ciani et al. (2015)[43]	Unknown - 2013	Scientific, Therapeutic,	Systematic review to assess definition of	Example Measures: degree of discontinuity (incremental, breakthrough), source of	Healthcare decisionmakers focused on static allocative	N/A

[4] ↑ (arrow up) symbolizes innovation is increasing, ↔ (sideways arrow) symbolizes innovation is constant, and ↓ (down arrow) symbolizes innovation is decreasing.

Product Type	Study Author(s)	Time Period	Measurement Method(s)	Method	Results	Conclusion on Innovation	Innovation Trend[4]
			Economic Measures	innovation for medical devices	innovation (emerging need, technology push), impact of innovation (patient benefits, quality of service, cost)	efficiency (efficiency at singular time point) instead of dynamic efficiency (accounts for new innovation), which underestimates returns on innovation.	
Device	Rejon-Parilla et al. (2022)[44]	Not listed	Scientific, Therapeutic, Economic Measures	Literature search to determine innovation definition and measurement method	Example Measures: added therapeutic value, step change, underlying health condition, safety, convenience, evidence base, impact to influence future R&D, economic impact	Decision makers need clearer definitions on innovation if using as criteria for pricing and adoption.	N/A

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