

2013-2015

IMPACT AUDIT

D-Rev

Newborn Health Program
Mobility Program

Findings and Executive Summary

Published September 26, 2017 • www.impactm.org/a/d-rev

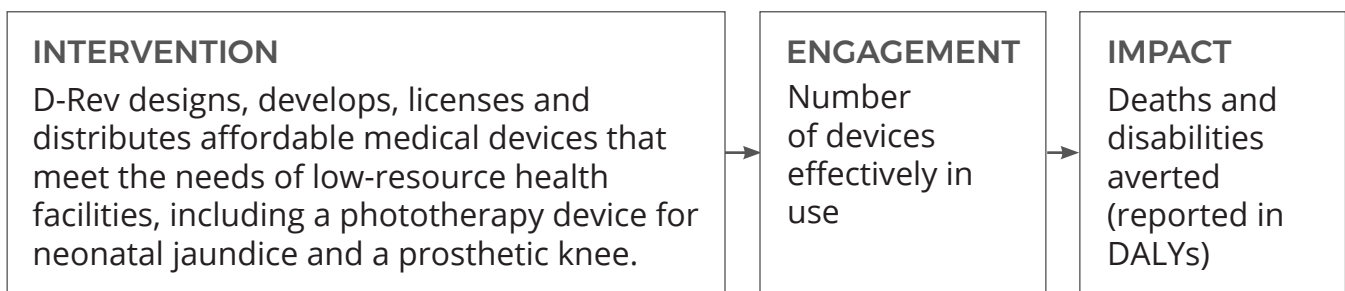


FINDINGS

Newborn Health And Mobility Programs

MISSION To improve the health of poor patients served by resource-limited medical facilities.

PROBLEM Medical devices on the market are too expensive for resource limited medical facilities.



IMPACT AND COST

Approximately
\$600 per DALY
averted

IMPACT AND COST CALCULATION

The impact of Brilliance is calculated using the number of patients treated over the device lifetime, the rate of reduction in kernicterus cases and the disability-adjusted life year (DALY) value of averting a case. The impact of ReMotion is the DALY reduction from untreated to treated limb amputations for the one month of ReMotion sales during 2013-15 period. In the average year from 2013-15, it cost \$22 million to avert 38,000 DALYs. Of that cost, D-Rev paid \$1 million and patients and hospitals paid \$21 million.

QUALITY OF EVIDENCE



QUALITY OF EVIDENCE ASSESSMENT

D-Rev produces a phototherapy device (Brilliance) for neonatal jaundice and a prosthetic knee (ReMotion Knee). There is strong clinical evidence that phototherapy improves outcomes. However, D-Rev has weak internal evidence on whether Brilliance is administered correctly, who it is administered to and whether they would otherwise receive treatment. Strong clinical evidence shows that prostheses such as D-Rev's ReMotion Knee improve outcomes. However, similarly to Brilliance, D-Rev has only low-quality internal evidence on its impact.

FINDINGS

Organizational Effectiveness

GEOGRAPHY 52 countries

STAGE Scale

AGE Current program model is 8 years old

SIZE Average annual sold 2013-15: 724 Brilliance devices; 73 ReMotion Knees

QUALITY OF MONITORING SYSTEMS

D-Rev's monitoring systems are adequate and often very good. However, several of D-Rev's systems have limitations that reduce accuracy. Most importantly, D-Rev only collects data from hospitals that are easy to reach and relies on assumptions about device use that may be out of date. As D-Rev delivers its devices through the market, data collection is challenging and costly.

Criteria	Credible	Actionable	Responsible	Transportable
ACTIVITY DATA	✓		✓	✓
TARGETING DATA		✓	✓	
ENGAGEMENT DATA		✓	✓	✓
FEEDBACK DATA			✓	✓
OUTCOMES DATA		✓	✓	

LEARNING AND ITERATION

D-Rev has an exceptional research and development process. Over the last three years, D-Rev has considered four changes to the design of its program and adopted three. Decisions to implement changes were supported by high-quality data and were arrived at systematically. Furthermore, D-Rev regularly researches and reviews new changes.

Criteria	Finding
ITERATION IS BASED ON DATA	Yes
DATA ARE OF HIGH QUALITY	Yes
ITERATION IS SYSTEMATIC AND PERIODIC	Yes

Table of Contents

Findings	2	Effectiveness of Brilliance	39
Executive Summary	6	Targeting for Brilliance	43
Nonprofit Comment	11	ReMotion Knee	44
Nonprofit Program Description	13	Effectiveness of ReMotion Knee	44
Mission	13	Targeting for ReMotion Knee	46
Theory of Change	13	Quality of Monitoring Systems	48
Problem	13	Rating	49
Activities	14	Activities	50
Assumptions	15	Targeting	51
Risks	16	Engagement	52
Measures of Engagement	17	Feedback	53
Measures of Impact	17	Outcomes	54
Program Details	18	Learning and Iteration	56
Geography	18	Rating	57
Stage	18	Products	57
Age and Scale	18	ReMotion Knee	57
Other Programs	19	Comet	58
How Donations are Used	19	Darkwing	59
Impact And Cost	21	Brilliance Pro	59
Findings	22	Product Design Process	60
Assumptions	23	Back Matter	61
Impact	26	Metadata	61
Cost	28	Monitoring Systems Scoring	62
Sensitivity Analysis	32	Glossary	63
Displacement and Other Effects	33	Reference List	74
Quality of Evidence	37		
Rating	38		
Brilliance	39		

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1460 Broadway
New York, New York 10036
www.impactm.org • info@impactm.org

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Feedback

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EXECUTIVE SUMMARY

Program Description and Top-level Findings

D-Rev improves the health status of poor patients in medically underserved locations by giving them access to inexpensive medical devices that meet their needs. D-Rev designs, develops, licenses and distributes affordable medical devices in pursuit of its mission. So far, it has produced a line of neonatal phototherapy devices (Brilliance) and a prosthetic knee (ReMotion Knee).

D-Rev has estimated its impact on patient health indirectly, because it does not have direct contact with patients, making difficult the collection of data. ImpactMatters has conducted similar calculations about D-Rev's impact, with some important adjustments that reflect our view of counterfactual impact. We draw mostly on data that D-Rev collects and on studies of the impact of medical devices elsewhere in poor countries. ImpactMatters measures impact in disability-adjusted life years (DALYs). In effect, we estimate by how many years patients suffer from disabilities plus how fewer years patients lose to premature death. DALYs account for the relative gravity of different disabilities. In calculating DALYs, each year lost to disability is weighted by the gravity of the disability.ⁱ

According to our calculations, the medical devices produced and distributed by D-Rev in the average year of our analysis period (2013-15) will improve health by about 40,000 DALYs over the lifetime of the device, at a total social cost of \$21 million.ⁱⁱ That cost figure includes both the device design and the cost of care. The cost-efficacy ratio for D-Rev's devices in aggregate is \$600 per DALY. Expressed another way, D-Rev devices prevented morbidity and mortality equivalent to one year of healthy life at a cost of \$600.

The Brilliance device has treated thousands of patients to date. The device itself is inexpensive to operate, and a one-time capital expense by the hospital of \$400-\$500

ⁱ Also, in calculating the time lost to disabilities over time, future disabilities are discounted, as would be done in purely financial calculations over time.

ⁱⁱ All currency conversions were performed using the World Bank's official exchange rates and are presented in 2016 U.S. dollars.

could last for 20 years. Most of the cost of care falls on patients or their insurance, who need to pay for inpatient neonatal care. A 2005 cost-effectiveness study found neonatal I.C.U. care costs \$800 adjusted for purchasing power per DALY in India and its neighboring countries, while we find that D-Rev's cost of *designing the Brilliance device alone* was just \$40 adjusted for purchasing power per DALY during the 2013-15 period. At this cost, designing a good device was as cheap as some vaccination programs. The device is therefore a cost-effective component of inpatient medical care, offering meaningful savings vis-à-vis commercially available devices. And in general, health interventions are considered highly cost-effective if they cost less per DALY than the average per capita income in a given country. At \$500, Brilliance falls well below the per capita income of \$1,680 in India, where most Brilliance devices are sold.

The cost-efficacy of the ReMotion Knee is tougher to judge because the device was still in the design phase during the 2013-15 time frame of the impact audit. During that time, just 267 devices were sold, and the annual cost per DALY of the ReMotion Knee was \$30,000 per DALY. But at the ReMotion production target of 2,600 units annually, cost efficacy looks dramatically better. At that rate, and if we hold costs of design and production at their 2013-15 levels, the cost efficacy would be \$1,200 per DALY.

Impact and Cost

Impact Corrected for Counterfactual Success

D-Rev's cost of impact was \$600 per DALY (\$600 to avert morbidity and mortality equivalent to one year of healthy life) during our analysis period. The D-Rev devices distributed in the average year allowed 50,000 patients to be treated over the lifetime of the device. The two devices currently in production are the Brilliance phototherapy device and the ReMotion Knee. All told, the two devices are expected to reduce premature death and disabilities by 40,000 DALYs, at a total social cost of \$21 million.

The impact of the Brilliance machine is an estimate of how many cases of kernicterus can be saved over the life of the devices, and is expressed in DALYs. The Global Burden of Disease study is the source of our estimate of the DALY weight, which D-Rev uses to calculate the DALY value of patients treated. Both ImpactMatters and D-Rev consider counterfactual impact, stating only the impact of care that patients would not have received in the absence of D-Rev's device.

Similarly, the impact of the ReMotion Knee is expressed in DALYs on a counterfactual basis. It uses the same source of reference data for the DALY weight of a ReMotion Knee,

and again corrects for counterfactual impact. Since just 267 knees were sold during the 2013-2015 audit window, the impact of the ReMotion Knee is much lower. Because the cost of design was still incurred, the cost-effectiveness ratio is high, at \$30,000 per DALY. We expect that this cost will drop to \$1,200 within a few years.

The estimated \$21-million-cost was borne by several partners, including D-Rev itself, hospitals that purchase the devices; and patients' out-of-pocket contribution. The \$500 estimate reflects the expected lifetime of the devices sold in an average year during the analysis period and the take-up rate of the device in actual field settings.

Another way to look at D-Rev's impact is to consider only the cost of designing the device, which is D-Rev's contribution to patient health. D-Rev, in designing and licensing medical devices, is one of many partners that work together to provide patient care, including the hospital, health payers, and the patients' families. D-Rev's cost of bringing Brilliance to market was \$40 per DALY averted. This is just one component of the cost to treat neonatal jaundice, and it is constant across the different health care markets where D-Rev licenses Brilliance for distribution. But all the \$40 per DALY bought was a device design; not the delivery of care to the patient. As long as the rest of the health care system is committed to treating neonatal jaundice patients, then the device design is considered extremely cost-effective.

Quality of Evidence

Though D-Rev does not regularly track patient outcomes, it does track the number of devices sold and installed. Based on published public health research and the total hours its devices have been in use, it estimates likely reductions in morbidity and mortality. Like any indirect health estimates, these inferences are as valid as the assumptions on which they are based: D-Rev's devices work in the field as they do in lab tests; D-Rev devices are used correctly in clinical settings; and devices reach the patients otherwise lacking access to comparable health care.

This audit draws on D-Rev's monitoring data, lab tests and field observations; third-party certifications; and high-quality studies from the medical literature. In the absence of a randomized controlled trial with D-Rev devices, there is plausible but not compelling evidence for D-Rev's impact. To calculate the impact of Brilliance, D-Rev has visited a sample of hospitals and carefully observed how devices are actually used. It then estimates the number of patients likely to suffer from neonatal jaundice, and the number

of patients that might otherwise not have had access to phototherapy for neonatal jaundice.

Our analysis differs from theirs in two ways. First, we derive a different estimate of the rate at which brain injury and death are prevented, based on the number of procedures performed. Second, we consider all the procedures that the devices will perform over the advertised lifetime of the device, discounting appropriately to the present. We were not able to resolve the main sources of uncertainty in the impact and cost estimates: whether patients are treated promptly; whether laboratory facilities support accurate diagnosis; whether clinical practice guidelines are followed; whether the patients treated with D-Rev devices would otherwise have had access to care; and whether the costs of the phototherapy procedure should be considered alone or with overnight hospital stays. A comprehensive study of these issues would be tremendously expensive, and is not likely to be completed soon.

Displacement

D-Rev regularly conducts market analysis to avoid tackling problems that others are likely to address. Given that investigation, it is unlikely that D-Rev is displacing other sellers of affordable, effective devices. On the contrary, anecdotal evidence suggests D-Rev is actually spurring competition in the market for affordable devices, bringing greater choice and lower prices to customers.

Quality of Monitoring Systems

D-Rev has acceptable and, often, very good monitoring systems. Yet it has trouble ensuring that its systems are valid, reliable and unbiased – in other words, that its data credibly capture actual program delivery. The two weakest aspects of D-Rev’s monitoring are: (1) collecting data from only those hospitals that are easy or inexpensive to reach, rather than using a representative sample; and (2) reliance on potentially outdated assumptions of the take-up of devices in actual use.

Learning and Iteration

D-Rev has an exceptional process for considering changes to its intervention. Its meticulous and structured R&D process ensures only those devices that are safe for human use and commercially viable make it to production; witness its testing process for Brilliance Pro. Its tests verified the design integrity, tensile safety, temperature safety, and luminosity, and other relevant standards. D-Rev is very selective in choosing which health problems to attack. It develops solutions only for diseases with high health burdens in developing countries, that can be treated with a simple device and that require minimal behavior change from patients and clinicians. Central as it is to D-Rev's mission, R&D is conducted year-round and is a fundraising priority.

NONPROFIT COMMENT

We thank ImpactMatters (IM) for its thorough and rich audit of D-Rev's systems and impact for 2013-15, including characterizing our strengths and identifying areas for improvement. As the smallest organization that IM has audited to date (\$1.7 million and 11 employees in 2016), we are encouraged that IM considers D-Rev to be at the most advanced stage of organizational development ("Scaling"), and thus held to their most rigorous standards. We hope that donors and other organizations see in D-Rev an example of a lean, dedicated team successfully leveraging limited resources for impact at global scale.

To add greater context to some of IM's findings, we offer the following comments:

- Presenting D-Rev's expenses (\$26/DALY averted) and the health system costs (\$550/DALY averted) as a combined figure, while standard in DALYs calculations, minimizes the fact that our model is built to leverage the market – not donors – for scaling. **In fact, D-Rev's cost efficacy per project increases over time – net costs taper off and impact grows – as products are released to market, and customers buy and use them to treat patients.**
- We are concerned that relying solely on a DALYs-focused impact and cost calculation for evaluating health interventions may discount the priorities of health professionals on the front lines. As a user-centered organization, D-Rev heavily weights the needs voiced by on-the-ground experts when selecting problems to address, even though those needs may not be among the most cost-effective to solve across all areas of global health. **We will continue to design for these health professionals because we believe that evidence-based approaches must be driven by the people directly facing the challenges posed by global health inequities.**
- We believe that using DALYs to compare diverse health interventions provides useful high-level information about cost-effectiveness, especially to policy makers. This notwithstanding, the global health sector stands to gain much from problem-level (e.g., jaundice management) DALY comparisons across the smaller range of organizations developing solutions. **N.G.O.s, universities, and for-profit enterprises with overlapping solutions should be evaluated and compared**

against one another to determine the most effective ways to solve a given problem.

We offer the following comments on areas that IM identified for strengthening:

- *Evidence quality:* Because there was already published clinical data verifying the effectiveness of our technological approaches, we did not prioritize validating these findings with our products during the audit review period (2013-15). **Starting in 2016 we began a series of rigorous evaluations in Rwanda, India, and Nepal that will improve the quality of our internal evidence.**
- *Monitoring systems:* While we have collected product usage and customer feedback from a range of health facilities, we have not been rigorously systematic in our sampling of facilities. **Thanks to IM's feedback, we have already started to better stratify our sampling of health facilities and have integrated this approach into our new product development process.**

D-Rev is committed to transparency and continuous improvement, and we hope others find IM's perspective as useful as we did. We welcome any questions or additional comments that readers may have and will continue to share our learnings for greater collective impact.

NONPROFIT PROGRAM DESCRIPTION

This section summarizes the nonprofit's mission and constructs a theory of change that describes the problem, the nonprofit's intervention and the appropriate measures of engagement and impact.

Mission

To improve the health of poor patients served by resource-limited medical facilities.

Theory of Change

PROBLEM

High-quality medical technologies developed and used in high-income countries are prohibitively costly for medical facilities serving poor patients. Even if those technologies are donated or sold cheaply second-hand, they can be inappropriate for low-resource facilities, which may not have the infrastructure and supply chains to support and maintain devices originally designed to be used in high-income countries. Meanwhile, low-cost alternatives available locally often suffer from poor quality. The result is a lack of medical technologies that are at once high-quality, context-appropriate and affordable for resource-limited medical facilities treating poor patients.

There are three key reasons why private and public actors do not already provide medical technologies to this target population:

HIGH RISKS AND LOW RETURNS

Private market players, faced with the prospect of high risks and low returns, choose not to invest in research and development (R&D) for medical devices in developing countries. Lack of financial transparency, weak contract enforcement, too much bureaucracy and inadequate infrastructure make running a business particularly challenging.¹ India, for instance, where the majority of Brilliance units are distributed, ranks 130th out of 190 countries in ease of doing business.² This risky environment is a barrier to entrepreneurs and investors who might otherwise start up R&D firms in developing countries.

POOR GOVERNANCE

Poor governance can lead to inefficient allocation of public resources and a lack of attention to public goods like R&D (and a legal and regulatory environment conducive to R&D).¹ Public R&D institutions tend to lack agility and competitive drive, and are likely to prioritize pure science over product design for commercial distribution. Their survival does not depend on the efficient fulfillment of market demands and as a result, public R&D efforts may not address the most pressing health issues facing the population.

POOR EDUCATIONAL ATTAINMENT AND LOW RETENTION OF QUALIFIED INDIVIDUALS

Low levels of educational attainment in developing countries impede innovation. And those who do complete higher education often emigrate to seek better opportunities abroad, known as the "brain drain" phenomenon. As of 2004, up to one-third of R&D professionals from developing countries were residing in O.E.C.D. countries.¹ The result is low rates of locally-driven innovation, especially of technologies tailored to country specificities.

ACTIVITIES

D-Rev designs, develops, licenses and distributes affordable medical devices, including a phototherapy device for neonatal jaundice treatment (the Brilliance product line) and a prosthetic knee (ReMotion Knee).

The Global Burden of Disease Study (G.B.D.) is the starting point of D-Rev's R&D strategy. D-Rev only pursues those diseases whose health burdens (1) exceed 100 million disability adjusted life-years (DALYs) in developing countries and (2) are twice as large in developing countries than in developed countries.^{3,4} (See Outcome Metrics below for a definition of DALYs.) The diseases that pass that this test are assessed on three axes: the putative health benefit of a device, D-Rev's capabilities and donor appetite. At this point, D-Rev

goes into the field, interviewing medical personnel and observing facilities, to verify its assumptions about user needs and learn about possible solutions for those diseases.⁵

After field visits, D-Rev maps out the possible technologies it could develop for the chosen diseases. Key decision-makers participate in "solution scoring" to systematically whittle down the list of technologies.⁶ Those with the best solution scores are developed sequentially through a five-phase design process. Over the course of the five phases, D-Rev produces a functional prototype of the product, conducts benchtop and field trials with the prototype and develops a final version of the product using the expected mass production process. At the end of each phase, the R&D team holds a phase review meeting to present its findings to other key decision-makers and a product advisory committee made up of industry experts. Any product being considered must receive approval from D-Rev's executives before it can progress to the next phase in the process.⁷

D-Rev develops a manufacturing and distribution plan in parallel with the product design process. D-Rev either partners with an established manufacturing and sales company to distribute products (e.g. for Brilliance) or contracts with a manufacturer and handles the supply chain in-house (e.g. ReMotion).⁸ When D-Rev does not have complete oversight of distribution, such as with Brilliance, it is not able to directly ensure products reach those in need. In those cases, D-Rev designs its licensing agreements to incentivize sales to public health facilities and "resource-limited countries," meaning those that rank "low," "medium" or "high," but not "very high," on the United Nations Development Program's Human Development Index.⁹

Depending on the distribution strategy chosen, either D-Rev itself or one of its partners secures the legal and regulatory approvals necessary to distribute the product in certain countries.⁸ Then, D-Rev creates and disseminates marketing materials to raise awareness of the product. It also identifies and reaches out to key opinion leaders and select customers to recommend and buy the product.¹⁰

Finally, D-Rev or its partners launch the product on the market, selling to a variety of customers: hospitals, clinics, governments and non-governmental organizations. D-Rev re-invests sales revenue into ongoing manufacturing, distribution, sales and marketing.¹¹

ASSUMPTIONS

In order for D-Rev's intervention to be effective, there are a number of assumptions that must be true about people and systems *not under D-Rev's direct control*, such as markets, D-Rev distribution partners, clinical partners and patients.

The first assumption is that clinical personnel are able to diagnose accurately and administer therapy correctly. They must be able to, in the case of Brilliance, recognize the clinical presentation of jaundice or interpret the results of a bilirubin blood test. Clinic staff must also understand the effective height range of the device head, the recommended therapy duration, protocols for protecting the newborn's eyes, protocols for individual treatment (one device, one baby) and so forth. Further, appropriate laboratory facilities make the likelihood of diagnosis higher. The most definitive test for jaundice is a bilirubin blood test, which requires a reliable laboratory. In the absence of a reliable lab, clinicians often use visual diagnosis, which is less reliable and may miss cases without visible symptoms.¹² The clinic must also have adequate infrastructure to support the new devices, such as electricity.

Brilliance, ReMotion and most other devices require some maintenance to live to their full service life. D-Rev predicts the LED bulbs in Brilliance last 7.6 years if used 14 hours a day.¹³ Based on independent field work, contracted by D-Rev, that found typical use is actually 5.4 hours a day, we estimate the LED bulbs last 19.7 years.¹² A ReMotion Knee lasts about five years before it needs to be replaced.¹⁴ These predictions rest on the assumption that users do not, for instance, abuse the Knees.

Lastly, D-Rev assumes its devices are commercially viable. That is, D-Rev assumes that when its devices are released on the market, there will be buyers and sellers who voluntarily enter into transactions with each other to obtain or sell the devices, each believing that benefits of the transaction are worth the costs.

RISKS

There are also several risks that D-Rev needs to address to ensure it delivers a high-quality intervention.ⁱ

First, D-Rev entrusts other organizations, such as Phoenix Medical Systems (henceforth "Phoenix"), with ensuring the mass-produced devices match the original technical specifications and quality standards set out in the R&D process. Therefore, D-Rev faces the risk that its manufacturing partners do not meet quality standards. But this risk is not particular to D-Rev: any device design company that relies on partners for manufacturing must manage this risk. D-Rev does so by partnering with companies that uphold

ⁱ The following risks were identified through ImpactMatters' research as well as interviews, documents and data collected from D-Rev. They are included here based on ImpactMatters' best judgment of the most relevant, likely and consequential risks that could interfere with impact. In contrast to assumptions, risks require more editorial judgment about importance.

international quality standards for the manufacture of medical devices (I.S.O. 13485:2003, I.S.O. 9001:2008, or both).¹⁵⁻¹⁷

Second, its distribution partners may not honor the agreed commercial terms, which stipulate maximum list prices, licensing fees and royalties owed to D-Rev per sale made. In particular, the agreement between D-Rev and Phoenix dictates pricing and royalty structures that incentivize sales to public facilities and countries with Human Development Index scores lower than “very high.” D-Rev risks not reaching its target population if Phoenix violates these terms.

Finally, D-Rev faces the risk that legal and regulatory approvals for its devices cannot be secured, perhaps due to bureaucracy, corruption, poor policy infrastructure or the nuances of bilateral trade relations. Indeed, D-Rev initially had trouble obtaining approval to export the India-made Brilliance device to Pakistan because of trade discrimination against goods made in India.¹⁰

MEASURES OF ENGAGEMENT

The following metrics track the delivery of, and participant engagement in, D-Rev’s program:

- Number of D-Rev devices sold
- Number of D-Rev devices distributed and installed
- Number of D-Rev devices effectively in use

MEASURES OF IMPACT

In this impact audit, the success of D-Rev's program is measured as the number of disability-adjusted life years (DALYs) averted due to D-Rev devices.

The World Health Organization defines the disability-adjusted life year (DALY) as equivalent to one year of healthy life. The DALY measure was developed by Christopher Murray and Alan Lopez in 1990 for the original Global Burden of Disease study, and it reflects both disability and premature mortality due to each disease or injury.^{3,18}

One DALY can be thought of as one lost year of “healthy” life. The sum of these DALYs across the population, or the burden of disease, can be thought of as a measurement of the gap between current health status and an ideal health situation where the entire population lives to an advanced age, free of disease and disability. DALYs for a disease or health condition are calculated as the sum of the Years of Life Lost (Y.L.L.) due to

premature mortality in the population and the Years Lost due to Disability (Y.L.D.) for people living with the health condition or its consequences.¹⁹

Program Details

GEOGRAPHY

As of the end of 2016, D-Rev had distributed Brilliance devices to the following countries: Bahrain, Bangladesh, Belgium, Colombia, Côte d'Ivoire, Ecuador, Germany, Ghana, Guatemala, Guyana, Haiti, India, Indonesia, Iraq, Jamaica, Jordan, Kenya, Kosovo, Lebanon, Liberia, Libya, Malawi, Malaysia, Morocco, Myanmar, Nepal, Nigeria, Oman, Pakistan, Peru, the Philippines, Rwanda, Sierra Leone, South Africa, Syria, Tanzania, Thailand, Togo, Tunisia, Turkey, Uganda, the United Arab Emirates, Vietnam and Zimbabwe.²⁰

By the end of 2016, D-Rev had distributed ReMotion Knees or ReMotion Knee prototypes to the following countries: Cambodia, Canada, Chile, the Dominican Republic, Ecuador, El Salvador, Ghana, Guatemala, Honduras, India, Indonesia, Mexico, Nepal, Nicaragua, Nigeria, Sierra Leone, South Africa, Thailand, Turkey and the United States.

D-Rev does not place any restrictions on which countries may receive its devices. However, it does focus greater attention on countries that score lower than “very high” on the Human Development Index.²¹

D-Rev is headquartered in the United States, where it coordinates ReMotion Knee sales in-house.¹⁰

STAGE

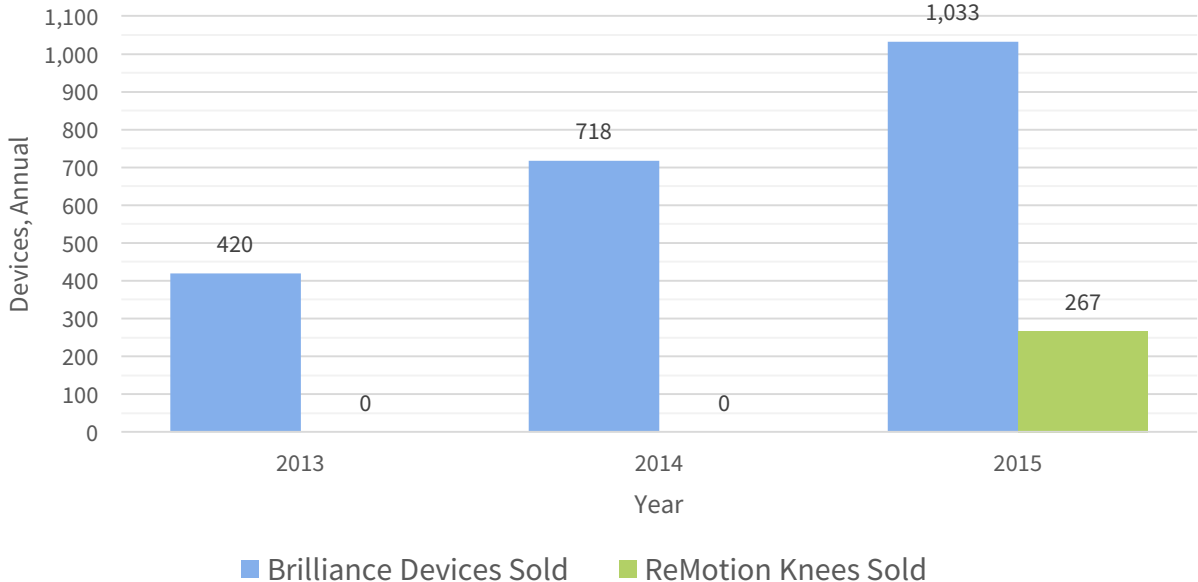
D-Rev is at the scale stage, meaning it has established its core program model and is now in the process of expanding it. D-Rev's stated strategy for 2016 and beyond is to "replicate a successful model."²² With early proof-of-concept in the areas of newborn health (Brilliance product line) and mobility (ReMotion and its precursors), D-Rev now aims to seed new products into its pipeline, scale up launched products, and begin to exit the market for products that prove sustainable without D-Rev's subsidization.

AGE AND SCALE

In 2008, its founding year, D-Rev concentrated on designing new medical solutions and explored six different product ideas, not all of which were viable beyond the design stage.

The turning point came in 2009, when D-Rev hired a C.E.O. and decided to cut two-thirds of those products, focusing just as much on distribution and market viability as it did on design. It was then that D-Rev began to resemble what it is today: a medical technology company with a carefully curated portfolio of low-cost, high-quality solutions.¹¹ This program model has been D-Rev's bedrock for the last eight years.

Figure 1. Brilliance and ReMotion Annual Output, 2013-15



D-Rev’s small staff of 11 leverage a market-driven model and partnerships with distributors to achieve scale. Sales of the Brilliance product line (Brilliance Classic and Brilliance Pro) have grown steadily over the audit period, 2013-15. Brilliance has been on the market since 2012. On the other hand, the ReMotion Knee did not launch in earnest until August 2017. Prior to 2017, most ReMotion Knees sold were part of field trials.

OTHER PROGRAMS

D-Rev does not run any other programs. R&D, which D-Rev calls "New Product Development," is considered a core function of D-Rev; new products under development are therefore not considered "other programs" but part of D-Rev's central intervention.

HOW DONATIONS ARE USED

New donor dollars are directed toward new product R&D, impact assessment, and operations. D-Rev earns revenue from the sale of Brilliance and ReMotion. Its goal is to use this revenue to fund the ongoing manufacturing, marketing, sale and distribution of

those devices, while reserving donations for its remaining essential activities, R&D and impact assessment.¹¹

IMPACT AND COST

WHY WE RATE

We produce a professional estimate of the program's impact and cost over a three-year window in order to quantify past program success.

HOW WE RATE

We calculate and report the estimated total impact of the program. Impact is reported as change in outcomes chosen by the nonprofit over a particular time period. Cost is reported as total social costs over the same time period. Impact and cost rely on the best available data and are reported but not rated or judged. Using total figures, we report a ratio of impact to cost.

Impact and cost estimates should be viewed in context of factors such as program stage and geography of delivery.

Impact includes all measurable changes in outcomes within the time period. Impact is calculated using a simple model that is based on the best available data on the effect of the nonprofit's program. We almost always use data from the nonprofit. Sometimes that data is combined with external studies. Very rarely, if internal data is of very low quality, we use only external data.

We include outcomes that are achieved in the time period but accrue in the future. We discount these future benefits by 5 percent. The length of future benefits is conservatively estimated based on available data. We report, but do not attempt to quantify, displacement, externalities and other contextual factors that could influence the impact of the program.

Total social costs include all costs to deliver the program. In addition to direct program costs, fixed costs from fundraising and management necessary to support the program are included. Costs borne by participants or costs paid by others are also included in total social cost. If a program earns commercial revenue, that revenue is netted out of costs.

Findings

D-Rev's total estimated impact from the units sold in the average year during 2013-15 is 38,000 disability-adjusted life years (DALYs) averted at a total cost to the health system of \$21 million. The cost of one DALY averted is approximately \$600. Considering D-Rev's own funds alone and not the expenditures of patients or other health care organizations, the cost per DALY averted is much lower, just \$40. Most of the impact is due to the Brilliance device, with the ReMotion Knee generating a small amount of impact, largely because it was only on the market for one month out of the three-year period under review.

Table 1. Impact and Cost Findings

Specification	Newborn Health	Mobility	Total
INDIVIDUALS TREATED PER YEAR	48,000	90	48,000
LIFETIME DALY AVERTED BY DEVICES PRODUCED IN AN AVERAGE YEAR	38,000	30	38,000
COST PER DALY, ALL STAKEHOLDERS	\$500	\$27,000	\$600
COST PER DALY, NONPROFIT	\$20	\$25,000	\$40

* All figures reflect averages of units sold in average year, 2013-15.

Dollars per DALY is an important and widely-used metric for cost efficacy in public health. It is by no means the only unit of measure, nor is it uncontroversial, but it has outstanding reference data. The World Health Organization regularly estimates the burden of disease for many public health problems, and assigns DALY weights to each disorder studied. The reference DALY weights data are meant to help with cost-efficacy analysis of public health interventions, so that researchers may have a common unit of measure for the value of treating thousands of different diseases. Cost-per-DALY analysis is important, but not the only way to make decisions about the allocation of resources in public health. It relies on ethical assumptions that have provoked much debate, such as valuing deaths differently depending on age at death. Rather than simply counting the number of deaths averted, DALYs value each death by the number of years of healthy life lost. In D-Rev's case, Brilliance is targeted at newborns, whose lives are more valuable in DALYs averted because they have many years left to live.

A Brilliance device could last 20 years at current utilization, about five hours of use per day. At that rate, each device can provide phototherapy for more than one thousand patients. In resource-limited facilities, we estimate that the counterfactual impact of each

machine is 50 DALYs averted, which is approximately equivalent to one life saved. Calculations are explained in detail below.

D-Rev predicts that each ReMotion Knee lasts three to five years. In developing countries, where access to prostheses is poor, we estimate the counterfactual impact of each ReMotion Knee is one-third of a DALY.

D-Rev's cost per Brilliance device is under \$1,000. Hospitals pay an average of \$500 per machine. But according to our calculations, patients' health care costs an additional \$50 per patient, or some \$1.5 million annually. The cost for patients' health care could be paid by patients, governments, philanthropists or insurers. As a result, the bulk of the costs of medical care related to jaundice management are not reflected in D-Rev costs.

The remainder of this section discusses the way we measure the impact of D-Rev's two current programs, Newborn Health and Mobility. We analyze the impact in common units (DALYs), based on the impact of the devices over their total lifetime, and using appropriate counterfactuals.ⁱ We present the cost of each device from two perspectives: first, what does D-Rev spend in order to make these devices available in the marketplace? D-Rev licenses medical devices for distribution, so one way to look at D-Rev is that its devices fill a gap in the medical device industry. Second, we analyze the cost of providing care to the patients that use D-Rev devices, taking account of all the costs borne by patients and payers, and avoiding double-counting of costs.ⁱⁱ

This audit considers financial and impact data reported in years 2013, 2014 and 2015. Following the headline findings on impact, we conduct sensitivity analysis.

ASSUMPTIONS

BRILLIANCE

The impact of Brilliance phototherapy machines depends critically on some factors that are beyond D-Rev's control. As a device company, D-Rev is not responsible for providing care to neonatal patients. The impact of the machines depends on how many patients are treated, the quality of care, the prevalence of hyperbilirubinemia and kernicterus, and whether the machines introduced into the market affect patients' access to care. That

ⁱ By *appropriate counterfactuals*, we mean an educated guess about how many of those patients would have obtained therapy even without D-Rev's devices.

ⁱⁱ By *double-counting*, we mean that we should not count both the cost of the doctor's fee and the bill issued to the patient to cover the same fee. The same fee should only be counted once as a cost of resources invested in patient care.

said, D-Rev has taken steps in its design process to increase patient access and the probability of effective care.

D-Rev makes reasonable calculations about the impact of each Brilliance device, although ImpactMatters uses more conservative assumptions about the impact of each procedure performed. ImpactMatters used D-Rev's own monitoring and evaluation data to estimate the utilization of its devices. D-Rev estimates the number of patients treated annually by a single machine from the total lamp time that machines are in use, and an average lamp time per patient.²³ From these, it works backwards to determine how many treatments per year each machine treats. Barrett Sheridan found that Brilliance machines are used for an average of 5.4 hours per day in 2014.²⁴ Thus each machine will treat on average 66 patients per year.

Of these 66 patients treated per year, how many would otherwise have received phototherapy treatment? D-Rev assumes that the additional number of patients treated who would otherwise have not been treated matches the rate of hospitals that lack effective phototherapy machines. For urban private hospitals, 80 percent of facilities in India lack effective phototherapy, and for both public and rural hospitals, the corresponding rate is 96 percent.²⁵ Therefore, for every 100 procedures conducted in private, urban hospitals in India, D-Rev assumes that 80 would otherwise not have been conducted. D-Rev cannot distinguish between hospitals that buy a Brilliance device to expand access to phototherapy, versus those that use Brilliance to replace an older device.

How many cases of kernicterus will be prevented by those 66 treatments? We use the number needed to treat (N.N.T.) to prevent a single case of neonatal jaundice from resulting in death or disability, using a clinical trial in the United States.²⁶ For every 222 patients treated, one death or disability will be prevented. It is worth noting that the N.N.T. calculations are highly sensitive to age, sex, and time when symptoms begin. Premature babies, male babies, and those with the earliest onset of symptoms have much lower N.N.T.s (as low as 10), whereas full-term, female babies with late onset of hyperbilirubinemia can have N.N.T. above 3,000. We also recognize that the N.N.T.s from an American clinical trial may not be appropriate for the 20-some countries where Brilliance devices are distributed, most of which are developing countries. But a similarly high-quality study of the N.N.T. in developing countries has not been conducted. Low- and middle-income countries have a higher prevalence of the top four risk factors for neonatal hyperbilirubinemia: prematurity, blood-group incompatibilities, the genetic G6PD deficiency, and infections.²⁷ This would tend to lower the N.N.T. On the other hand, babies in developing countries might arrive at facilities with hyperbilirubinemia that is beyond

treatment, thereby raising the N.N.T. Without a credible way of quantifying these contradicting factors, we choose to use the original 222 figure.

The clinical efficacy of phototherapy in lowering blood serum bilirubin is 84 percent.²⁶ The remainder of patients require further therapy, such as exchange transfusions, to control symptoms and prevent long-term injury or death. The N.N.T. calculations from the clinical trial in the United States are based on combined phototherapy with additional therapies, and not for phototherapy alone. We therefore adjust the N.N.T. calculation by the efficacy of phototherapy alone, leading to an estimate of one case prevented per 264 patients treated by Brilliance.

D-Rev uses a different approach that reflects the burden of kernicterus from neonatal jaundice by geographic region. While it is commendable that D-Rev uses regional burden of disease statistics to calibrate its estimate of impact, there are several important assumptions that thus far have not been well-studied. These assumptions, if well-studied, would improve the quality of the impact estimate. They include: How accurately are patients referred for phototherapy? Are false positive or false negative diagnoses more prevalent among those referred for treatment? What are the patients' gestational age at birth, sex, and time of onset of symptoms?

We use the Global Burden of Disease's DALY weight of death or permanent disability from kernicterus. The Global Burden of Disease sets the DALY weight of kernicterus at 0.434, equivalent to that for cerebral palsy.²⁸ D-Rev explains further that 10 percent of patients with kernicterus die of complications, and that among the remaining 90 percent the weighted life expectancy is 30.5 years. So, the expected value (in DALYs) of averting one death or disability from kernicterus is 19 DALYs.

Brilliance machines are thought to be durable. The component most vulnerable to failure is the lamp itself. The LED bulbs used for the lamp have a service life quoted at 19.7 years, as a multiple of the time the LEDs are actually illuminated.²⁹ Sensitivity analysis shows that the device longevity has a small effect on the cost per DALY. If the device longevity were just seven years instead, the total cost of impact would be reduced by just 5 percent, because the bulk of costs associated with treatment falls on patients or their insurance. ImpactMatters uses a 5 percent social discount rate for both costs and benefits.ⁱ

ⁱ The social discount rate is a reflection of all rational, economic actors' preference for returns realized today over returns tomorrow. The standard ImpactMatters rate in the base case is 5 percent per annum, in keeping with the standard used by the World Bank. Other discount rates of 2 percent and 10 percent have been proposed for various contexts and social ends. The extreme case, 50 percent, is included out of deference to skeptics who are not interested in costs and benefits to be realized a decade or more hence.

REMOTION

While thousands of JaipurKnees have been fit, very few ReMotion Knees had been sold during the audit period. No ReMotion Knees were sold in 2013 and 2014; 267 knees were sold in December 2015, when the knee went to market. At the end of 2015, D-Rev projected sales of 1,695 in 2016 and 5,710 in 2017.³⁰

Each amputee fitted with a prosthesis shows a reduction from a DALY rate of 0.173 for untreated lower limb amputation to a DALY rate of 0.039 for a treated amputation.³¹ The DALY weight is applied to each year of life lived with a medical condition.

How long do ReMotion Knees last? The devices remain in use for five years. The average age of amputees at fitting is 29.³² The devices are engineered to last for 3 million gait cycles, sufficient for up to five years of use.³³⁻³⁵ Rather than model explicitly the distribution of patient death and device failure over time, we simply take the lower of the two expected values, that is, patient remaining years of life and device remaining years of service. Each kind of device can provide five years of reduced DALY weights.

Not all patients would otherwise have gone without treatment. The ReMotion survey data shows that only 57 percent of patients had no alternative prosthesis prior to fitting.³² Some patients also abandon their prostheses, if they find them uncomfortable or ill-suited to their work and lifestyle. 90 percent of amputees fitted with ReMotion continued to use the knee six months after fitting, an improvement from the 79 percent figure for ReMotion's predecessor, JaipurKnee.^{36,37}

IMPACT

The impact of each D-Rev program is expressed in DALYs averted.

BRILLIANCE

The impact of the Brilliance device is the total value of morbidity and mortality prevented by phototherapy. The impact is valued in DALYs and calculated as the total morbidity and mortality that will be prevented by the average number of devices sold annually in 2013-15, discounted to present value. The approach is summarized in Equation 1. Each machine sold during this period is expected to avert approximately 4.16 cases of kernicterus over its 20-year device life. The total number of machines sold annually is approximately 724. The present value of the aggregate impact of those machines over the device's life is 2,000 deaths and disabilities averted, or 38,000 DALYs.

Equation 1. Annual impact of Brilliance

To calculate the annual impact in DALYs I of Brilliance, we use the following equation:

$$I = ABCDE$$

Symbol	Variable	Value
A	Patients treated in one year by average annual sales of Brilliance devices	48,000
B	Success rate of phototherapy in reducing bilirubin levels	84%
C	Rate of kernicterus cases saved per successful phototherapy	0.45%
D	DALY value of a successful treatment	19
E	Additionality, an adjustment for counterfactual access to phototherapy	85%

The total number of treatments provided in one year, A , is the product of the number of devices sold per year (724) and the number of patients each is expected to treat annually (66).^{23,24,29} Phototherapy's clinical efficacy, B , in treating hyperbilirubinemia is expressed as a percentage (84 percent).²⁶ High bilirubin leads in some cases to kernicterus, a potentially fatal brain injury. The DALY value of successful treatment depends on the success rate, C , at which treating hyperbilirubinemia prevents kernicterus (one case per 222 patients), and the DALY weight, D , of each kernicterus case (19).^{26,31} Finally, at E , we follow D-Rev's assessment of how many patients would otherwise have had access to phototherapy, (85 percent).^{23,38} The average annual impact of Brilliance was therefore approximately 2,900 DALYs from 2013-15.

Over the almost 20-year device lifetime, the total impact of the Brilliance units sold in the average year from 2013-15 is expected to be 38,000 DALYs, discounted to present value by 5 percent per annum.

REMOTION

The impact of the ReMotion Knee is the value of all the prostheses fitted annually. The value is expressed in DALYs, adjusted for counterfactual access, counted over the lifetime of the device, and discounted to present value. The approach is summarized in Equation 2. Each ReMotion Knee fitted has a value of approximately one-quarter of a disability-adjusted life year, and an average of 90 were fitted annually during the years under audit.

Equation 2. Annual impact of ReMotion Knee

To calculate the annual impact in DALYs I of ReMotion Knee, we use the following equation:

$$I = ABC$$

Symbol	Variable	Value
A	Patients treated in one year by average annual sales of ReMotion Knees	80
B	DALY value of a treatment	0.13
C	Additionality, an adjustment for counterfactual access to prosthesis	57%

Of 90 patients treated annually, about 80 continue to use the device. That figure is multiplied by the DALY value (0.13) of a treatment.³¹ 57 percent of D-Rev's surveyed patients stated that they had never before had access to a prosthesis.³² The average annual impact of ReMotion Knee was therefore approximately 6 DALYs from 2013-15.

Assuming patients use ReMotion to the end of its five-year lifetime, the total impact of the ReMotion Knees sold in the average year from 2013-15 is expected to be 30 DALY, discounted to present value at 5 percent per annum.

COST

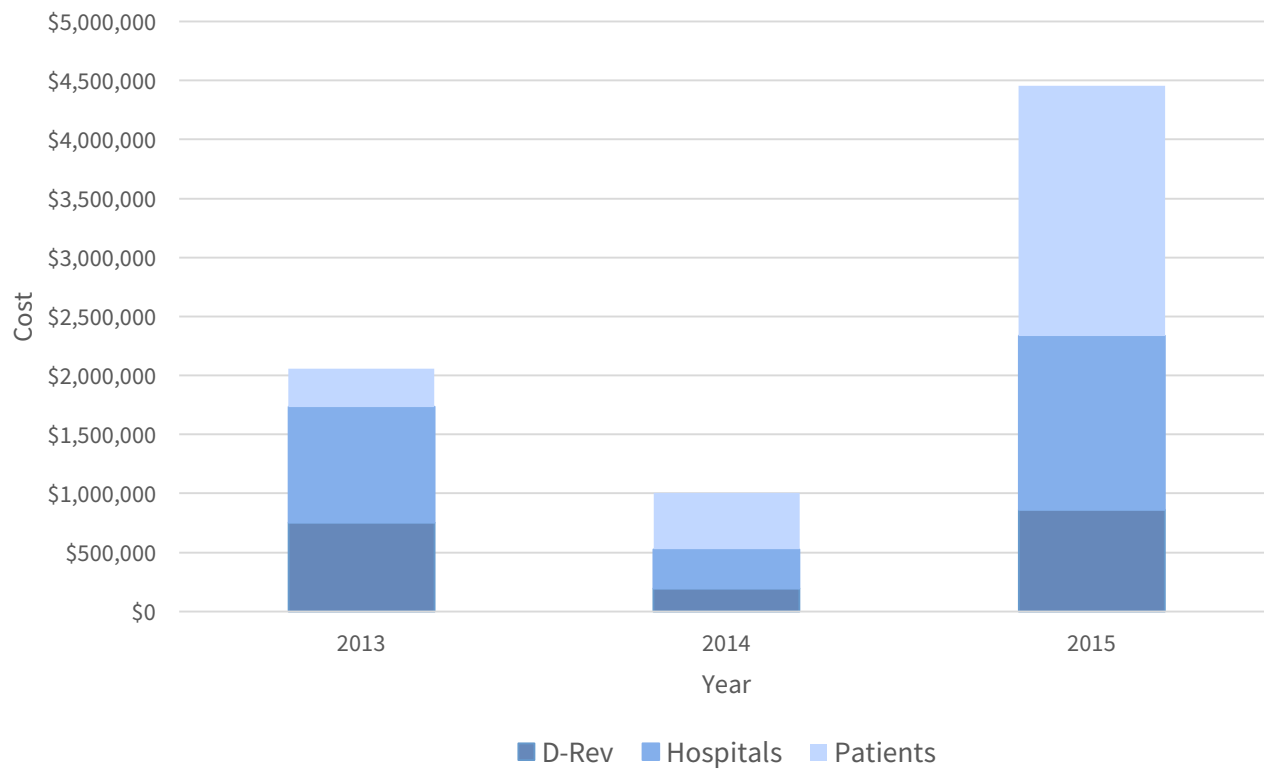
The three-year trailing average of D-Rev's gross expenses in 2013-15 was \$1.4 million. D-Rev's average annual revenue from commercial licensing and other sources was \$31,000. The best measure of charitable funds invested in D-Rev's operations is expenses net of commercial revenue: an annual average of \$1.4 million in 2013-15.

Annually, the Brilliance program cost D-Rev \$690,000 to operate. Health care facilities paid \$336,000 annually to purchase the devices. Beneficiaries and other health payers such as governments paid the lion's share of the costs, approximately \$1.5 million annually. The cost of the Brilliance program to D-Rev is falling rapidly because the device requires less research and development. D-Rev does not produce and distribute the device, so program costs will remain low.

Brilliance has seen a 146 percent increase in partner and beneficiary costs over the past three years, while the costs to D-Rev have fallen by 57 percent. D-Rev has largely

completed its work on the design of the Brilliance device. Most of the cost of production now falls to Phoenix, the manufacturer and distributor who recovers cost through sales. Hospitals and health systems continue to buy the devices. Patients obtain care through hospitals with no direct links to D-Rev. As a result, the ratio of impact to total cost may remain flat indefinitely, but D-Rev's internal costs will continue to fall as day-to-day operations wind down.

Figure 2. Costs of Brilliance program, 2013-15, shares by payer



The cost to purchase Brilliance around the world averaged \$336,000 from 2013 to 2015.³⁸ That revenue largely was largely paid to manufacturer and distributor Phoenix and not to D-Rev. The cost of new Brilliance machines is a distinct marginal cost included in the cost of delivery.

Phototherapy for neonatal jaundice is only provided with inpatient medical care. Emergency neonatal care, a set of therapies that includes treatment for neonatal jaundice, had an incremental cost-effectiveness ratio of more than \$800 adjusted for purchasing power per DALY averted in India and its neighboring countries, according to a British Medical Journal study.³⁹ This figure is considerably lower than Brilliance's \$2,000 total cost, adjusted for purchasing power, per DALY averted. The disparity may be due, at least in part, to differences in costing methods. While the published study also includes costs to the health system and to patients, details such as whether patients paid for private care

and whether patients' opportunity cost of time were included were not reported. The degree of comparability to our analysis is therefore unknown.

Patients spent \$1.5 million annually on Brilliance phototherapy during 2013-15.²⁴ All currency conversions were performed using the World Bank's official exchange rates. Most patients require two additional days in the hospital in order to receive the full 40-hour treatment. The cost of this care in private hospitals plus the value of one parent's foregone wages is \$46 per patient.^{40,41} The cost is applied to 67 percent of patients who obtain care in private hospitals, but not to the remaining one-third who obtain care in the public health system. It is not clear what the correct price of care would be for patients in the public health system, so that cost is simply omitted. As a result, the estimate of patient costs could be too low by as much as half the current estimate.

Considered as a device design alone, Brilliance would be highly cost-effective at \$20 per DALY. According to a study of cost-effective medical interventions in low- and middle-income countries, the interventions that could save the most maternal, newborn and child lives at the lowest cost are skilled birth attendants and emergency obstetric care, at a cost of about \$20 per DALY averted (in U.S. dollars 2000) – comparable to the cost-effectiveness of D-Rev device design.⁴² The study used the World Health Organization's CHOICE methodology, which counts "program-level" costs of implementing interventions and "patient-level" costs of obtaining care, as does ImpactMatters' methodology. But D-Rev's \$20 cost only brings the design to market. It does not deliver care to the patient. Nonetheless, at a total cost of \$500 per DALY, Brilliance is still considered highly cost-effective by traditional cost-efficacy thresholds:⁴³ it is lower than the per capita income of \$1,680 in India,² where most Brilliance devices are sold.

During the audit period, ReMotion had an average annual cost to the nonprofit of \$700,000, including direct and indirect costs. In the three years from 2013 to 2015, ReMotion direct costs increased only slightly from \$450,000 to \$500,000 and then fell again. Most of the products distributed historically in this product line are not the current generation of ReMotion Knees.

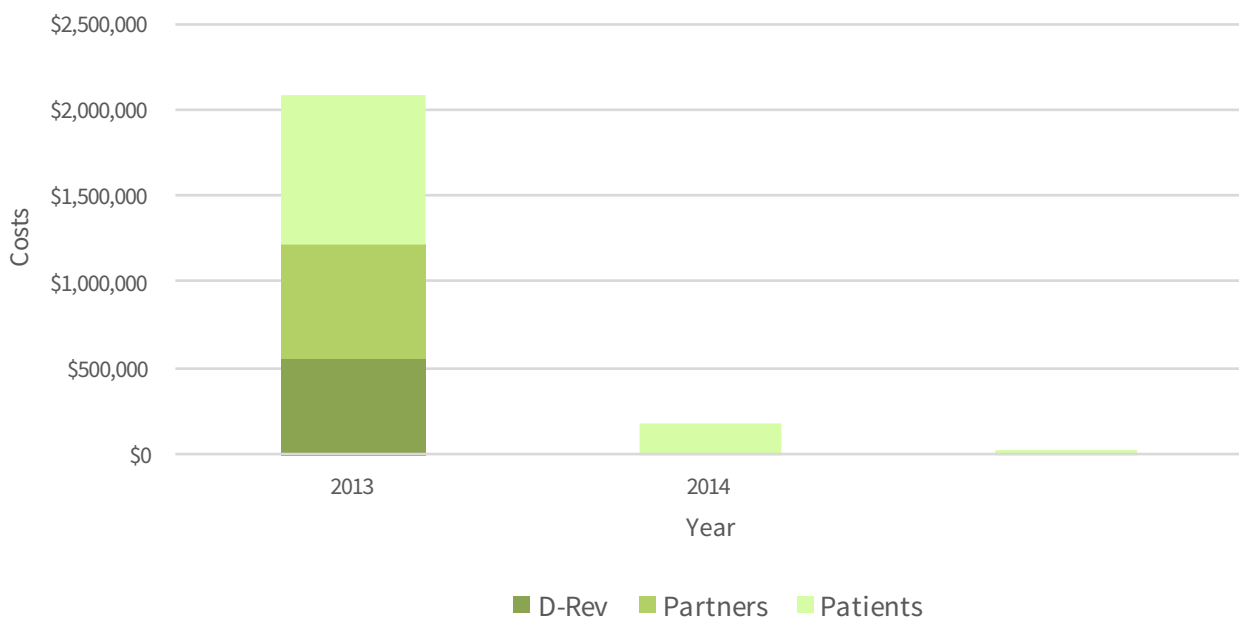
The cost of clinicians' time to fit amputees with the ReMotion Knee, or to provide occupational therapy and psychologic support is typically covered by non-governmental organizations, governments, patients, or even donated by the clinician herself. But the amount of time contributed and how various parties split that time cost are unknown. The only hard data provided thus far are the cost of an evaluation conducted jointly with a local health organization, Bhagwan Mahaveer Viklang Sahayata Samiti.

The current trial of the ReMotion Knee costs \$180,000 to one of D-Rev's partners, beyond funds that appear in D-Rev's budget.⁴⁴ The grant that funds that trial also contains funds

for D-Rev, which are captured in the discussion of D-Rev costs above. These costs appear as partner costs.

ReMotion has a target price of \$80 per device. During the audit period of 2013-15, ReMotion was on the market for just one month, December 2015, during which D-Rev sold 267 units. Said differently, D-Rev sold an average of 90 units annually during the three-year period, or equivalent to about \$21,000 in participant costs. Current projections of ReMotion Knee sales estimate approximately 3,271 devices will be sold annually over 2017-19.⁴⁵ At a price of \$80, that would correspond to an annual cost of \$264,000 for patients or their benefactors to purchase the prostheses.

Figure 3. Costs of ReMotion Knee program, 2013-15, shares by payer



The ratio of total cost to impact for ReMotion is \$27,000 per DALY. This ratio is not a good guide to the cost-efficacy of D-Rev for several reasons. First, it looks only at the cost to impact ratio of the ReMotion Knee during its design phase, before production has been scaled up. The number of knees fit during the audit (267) is less than 10 percent of the annual production target for 2017-19 (3,271).

If we model instead the cost of ReMotion with a far greater number of devices, we can forecast that the cost per DALY will be lower in the future. The forecast is only as good as its assumption, of course. Assuming D-Rev hit its sales targets originally set in 2015 for 2016 and 2017, then the total social cost per DALY would fall to \$1,200. As a component of that figure, the cost of the device design alone is \$900 per DALY.

Sensitivity Analysis

Our estimate of impact relies on several key assumptions. We analyze the effect of two those key assumptions, the discount rate and the longevity of devices, by calculating how different values change the cost per DALY.

For both assumptions, the cost per DALY varies very little across a wide range of values. However, when partner and beneficiary costs are excluded and only D-Rev's cost are considered, the cost per DALY varies as much as five times between the lower and upper range of values for both assumptions.

Table 2 analyzes the sensitivity of impact and cost to the social discount rate.

The total cost per DALY of D-Rev is relatively stable across a wide range of discount rates from 0 percent to 50 percent, varying from \$500 to \$800 per DALY. As the discount rate rises, the simple cost of impact rises much faster, from \$20 at zero discount to \$160 per DALY at 50 percent. D-Rev's costs are realized in the present; whereas the benefits of future phototherapy and mobility devices will not be realized for years. A higher discount rate shrinks the value of future impacts relative to costs realized today. The same is not true of beneficiary costs, which will be realized at some distance in the future. At higher discount rates, the ratio of D-Rev's costs to other stakeholder costs drops somewhat, by the same reasoning.

Table 2. Sensitivity to Discount Rate

Device Longevity in Years*	0%	5%*	10%	15%	50%
COST PER DALY	\$500	\$600	\$600	\$600	\$800
COST PER DALY, D-REV ONLY	\$20	\$40	\$50	\$70	\$160
BRILLIANCE IMPACT (DALY)	57,100	37,600	27,000	20,800	8,700
REMOTION IMPACT (DALY)	30	30	30	20	20
COMBINED IMPACT	57,100	37,600	27,000	20,800	8,700
NONPROFIT COST	\$1.4M	\$1.4M	\$1.4M	\$1.4M	\$1.4M
PARTNER COST	\$400K	\$400K	\$400K	\$400K	\$400K
BENEFICIARY COST	\$29.3M	\$19.3M	\$13.9M	\$10.8M	\$4.9M
TOTAL COST	\$31M	\$21.1M	\$15.7M	\$12.6M	\$6.7M

* Base case

Table 3 analyzes the sensitivity of impact and cost to the longevity of the device.

The total cost of impact is not highly sensitive to the longevity of the device. Over a span of simulations from three years to 20 years in duration, the cost per DALY varied by less than 20 percent. Costs to D-Rev and health providers stay constant, while the cost of medical treatment borne by patients or their insurance rises.

Table 3. Sensitivity to Device Longevity

Device Longevity in Years*	3	5	7	10	20*
COST PER DALY	\$700	\$600	\$600	\$600	\$600
COST PER DALY, D-REV ONLY	\$170	\$110	\$80	\$60	\$40
BRILLIANCE IMPACT (DALY)	8,300	13,200	17,600	23,500	37,600
REMOTION IMPACT (DALY)	20	30	30	30	30
COMBINED IMPACT	8,300	13,200	17,600	23,500	37,600
NONPROFIT COST	\$1.4M	\$1.4M	\$1.4M	\$1.4M	\$1.4M
PARTNER COST	\$400K	\$400K	\$400K	\$400K	\$400K
BENEFICIARY COST	\$4.1M	\$6.5M	\$8.6M	\$11.5M	\$19.5M
TOTAL COST	\$5.8M	\$8.2M	\$10.4M	\$13.3M	\$21.3M

* Base case

Displacement and Other Effects

This section discusses impacts other than the health benefits to patients. It begins with a discussion of side effects from phototherapy treatment. Next, we consider benefits or costs to other individuals and businesses who are affected by the new devices.

Displacement refers to individuals and businesses that are hurt by competition with D-Rev devices. Externalities might refer to, for example, the benefits of economic growth, or the benefits to dependents when a prosthesis helps an amputee earn more.

BRILLIANCE: SIDE EFFECTS

NEGATIVE, LOW IMPORTANCE

Recent evidence suggests a very low prevalence of minor, reversible short-term side effects of neonatal blue light phototherapy, such as skin burns, skin rash, purpuric and bullous eruptions, diarrhea, bronze-baby syndrome, temperature instability, electrolyte disturbance, disorder of circadian rhythms, and interference with maternal-infant interaction.⁴⁶ Researchers caution that side effects considered benign in mature neonates can have serious complications in infants with extremely low birth-weight (less than or equal to 750 g), citing a study⁴⁷ that found an increased risk of mortality on extremely low-weight infants treated with aggressive phototherapy. Aggressive therapy means commencing phototherapy as soon as total serum bilirubin levels in the baby's blood are greater than or equal to 5 mg/dL, compared to the usual 8 mg/dL cut-off in conservative phototherapy.⁴⁸ However, there is no evidence that hospitals with Brilliance administer aggressive phototherapy to babies with extremely low birth-weights.

Studies also indicate the possibility of long-term adverse effects like increased risk of childhood asthma, melanocytic nevi (birth marks or moles) and retinal damage.⁴⁸ However, more research is needed to confirm findings about long-term effects.

Given that the evidence for long-term effects is inconclusive, that short-term effects are minor and reversible, and that aggressive phototherapy can be avoided for babies of extremely low birth-weight, it is likely the benefits outweigh the negative side effects of phototherapy. Phototherapy remains an effective treatment for neonatal jaundice and has been shown to reduce the levels of bilirubin in the neonate.⁴⁹ Compared with the benefits, the importance of negative side effects is considered low.

One factor that disrupts this balance of health benefits to side effects is false diagnosis of jaundice. It is possible, though not documented, that clinicians could over-prescribe phototherapy without prompt and accurate laboratory screening. The A.A.P. guidelines for phototherapy depend on postpartum age and serum bilirubin tests.⁵⁰ There is some concern that universal screening may drive up rates of phototherapy without lowering bilirubin encephalopathy.⁴⁹ If this is the case, the side effects of phototherapy might warrant further attention. However, D-Rev has not observed overtreatment in its markets; rather, it has found there is a *lack* of effective screening, which leads to babies going untreated.

BRILLIANCE: DISPLACEMENT AND COMPETITION

POSITIVE, LOW IMPORTANCE

D-Rev's strategy for sustainability is to sell rather than donate medical devices to both private and public customers. As a consequence, low-quality devices may get driven out of the market, high-price devices may lose some but not all of their market share, and there may be new low-price, high-quality entrants to the market.

However, D-Rev has found instances where corruption and cronyism caused some hospitals in India to choose more expensive devices over Brilliance.⁵¹ And even though D-Rev sets a capped price of \$400-\$500 for Brilliance, there have been cases of distributors marking the price up to \$2,400.⁵¹ D-Rev has since partnered more closely with Brilliance manufacturer Phoenix to better educate customers, and has intensified its process for vetting supply chain partners. D-Rev suspects it has had some preliminary effect on the market, including influencing a major competitor to drop the price of its phototherapy device in India.¹¹

Because D-Rev does not yet have results from systematic and credible studies of its market effects, the importance of these positive effects is currently considered low.

BRILLIANCE: ADDITIONAL DEMAND FOR HEALTH

AMBIGUOUS, LOW IMPORTANCE

Hospitals may have an influx of patients, and therefore revenue, as a result of the newly affordable phototherapy device. The cost of that medical care is borne by patients, governments and insurance providers; but the benefits of the therapy outweigh the cost.

On the other hand, hospital capacity may be limited, in terms of beds, laboratories, and staff. Independent field work contracted by D-Rev found anecdotal evidence of public hospitals in Kerala, India, with extremely crowded neonatal intensive care units.²⁴ Adding a new treatment - phototherapy - could raise costs or cause delays for other patients in the same facility. But extreme overcrowding was observed in *regional* hospitals, so equipping district-level and community hospitals with more phototherapy devices should also reduce referrals to such overcrowded facilities in the first place.

REMOTION: DISPLACEMENT AND COMPETITION

POSITIVE EFFECTS OF LOW IMPORTANCE

There are only two other known low-cost, polycentric prosthetic knees in the market besides the ReMotion Knee. The LIMBS M3 Relief Knee, produced by LIMBS International, has a production cost of \$100; its selling price is unknown.⁵² LIMBS International partners

with clinics and nonprofits to deliver and fit the M3 Relief Knee in Guatemala, Kenya, India, Ecuador, Bangladesh, Senegal, Bolivia, the Dominican Republic and Mexico. The JaipurKnee is the predecessor to ReMotion, but is still in production at B.M.V.S.S., the exclusive manufacturer. B.M.V.S.S. provides both JaipurKnees and ReMotion Knees at no cost to patients in India. Apart from LIMBS, JaipurKnee and ReMotion, developing-country markets offer primarily single-access prosthetic knees, which are ergonomically inefficient and have poor stability. It is plausible the ReMotion Knee will inspire more competitors offering polycentric knees and eventually displace single-access knees. But since ReMotion has not had sufficient time on the market, D-Rev has yet to study its market effects in a systematic and credible way.

REMOTION: ECONOMIC GROWTH

POSITIVE EFFECTS OF MODERATE IMPORTANCE

The ReMotion Knee is likely to generate economic growth by creating a more productive workforce: more amputees will be able to return to work and perform a wider range of work functions, including farming and manual labor, and their caregivers will be able to spend more time working as well. There is no evidence that prostheses such as the ReMotion Knee impose unaccounted costs on third parties.

QUALITY OF EVIDENCE

WHY WE RATE

Quality of evidence captures confidence in the impact and cost estimates. For programs with high quality evidence, the impact and cost estimates are more likely to accurately reflect the effectiveness of the program. Nonprofits delivering interventions with lower quality of evidence may still be achieving impact, but there is less proof to substantiate that impact.

HOW WE RATE

Evidence can either come from internal data collected directly on the nonprofit’s program (“internal evidence”) or from data collected on interventions similar to the nonprofit’s program (“external evidence”). When considering internal evidence, we look at the quality of that evidence. When considering external evidence, we look both at the quality of the evidence and the relevance of that evidence to the nonprofit’s program. We assess evidence based on the stage of the program:

- Design Stage:** The program model is undergoing change.
- Validation Stage:** The nonprofit is testing the program’s impact.
- Scaling Stage:** The nonprofit is in the process of expanding its program.

We rate nonprofits at the scaling stage using the following criteria:

External Evidence	Internal Evidence			
	NONE	LOW QUALITY	MEDIUM QUALITY	HIGH QUALITY
NONE	☆☆☆	★☆☆	★★☆	★★★
LOW QUALITY	☆☆☆	★☆☆	★★☆	★★★
MEDIUM QUALITY	★☆☆	★★☆	★★☆	★★★
HIGH QUALITY	★☆☆	★★☆	★★★	★★★

Rating

D-Rev earned two stars for evidence of medium quality. There is very strong clinical research on the impact of the main devices it produces: a phototherapy device for neonatal jaundice (Brilliance) and a prosthetic knee (ReMotion Knee). However, some problems remain. To date, D-Rev has not collected health data on patients treated by Brilliance. It has weak evidence that Brilliance is administered correctly by clinicians. To estimate impact, it uses strong assumptions based on early field work about the counterfactual, meaning how many babies would have had access to phototherapy absent Brilliance. Still, the quality of evidence for Brilliance is medium and not low, because there is good clinical evidence that phototherapy is an effective treatment for neonatal jaundice. A rigorous evaluation of Brilliance is underway, however, in Rwanda. Comparable problems face the ReMotion Knee. Prosthetic knees are shown to improve patient outcomes in external literature, but D-Rev so far has only low-quality internal evidence about its impact on patients.

D-Rev’s two programs, Brilliance and ReMotion Knee, were audited independently for impact. The programs consume similar staff time and budget. D-Rev cumulatively spent almost equal amounts on both devices during the audit period. It happens that the programs also have equally strong evidence, in that evidence generated by D-Rev is limited in both cases, but evidence from the medical literature is of high quality and high relevance. Neither program has completed a third-party evaluation to date, although a third-party evaluation of Brilliance is now underway.

Table 4. Quality of Evidence Rating Rubric

Type of Evidence	Brilliance	ReMotion Knee	All Programs
INTERNAL EVIDENCE	Low Quality	Low Quality	Low Quality
EXTERNAL EVIDENCE	High Quality	High Quality	High Quality
CORRESPONDING RATING			★ ★ ☆

Brilliance

Infant jaundice is a common condition that occurs when there is excess bilirubin in the blood. Extremely high levels of bilirubin can lead to brain dysfunction (kernicterus) and death. Phototherapy has been shown to effectively reduce bilirubin levels and greatly reduce the chances of kernicterus and death. Its clinical efficacy is widely accepted in the medical literature. D-Rev has developed a phototherapy device, Brilliance, of which it sold an average of 724 units annually in 2013-15. By our calculations, these units effectively treat 48,000 babies over the device lifetime and avert 38,000 DALYs. But while the evidence for phototherapy in clinical research is very strong, it is weaker for Brilliance as a device. D-Rev does not routinely monitor how well clinicians follow clinical practice guidelines when administering phototherapy using Brilliance. D-Rev's calculation of how many patients are treated is extrapolated from a series of site visits from an ultimately non-representative sample of hospitals, though laudable effort was made to sample from public, private, rural and urban settings across India. Importantly, D-Rev does not routinely collect data on patient health outcomes after receiving Brilliance phototherapy. Nor does it have a robust estimate of the counterfactual, meaning how many babies would otherwise have access to phototherapy. Without patient health outcomes and a meaningful counterfactual, it is difficult to estimate D-Rev's impact with confidence.

While there is no evidence of health impact from tests on human subjects yet, D-Rev is in the process of generating that evidence in a study in Rwandan hospitals.

EFFECTIVENESS OF BRILLIANCE

Phototherapy is an effective treatment for neonatal jaundice, which is caused by high levels of bilirubin in the blood.⁴⁹ Intensive phototherapy has been shown to reduce the levels of bilirubin in the neonate. 84 percent of patients treated with phototherapy in modern settings maintain bilirubin levels below a critical threshold and require no further treatment.

One of the differences between the findings of this audit and D-Rev's claims about the impact of Brilliance hinges on the rate at which phototherapy prevents kernicterus, the brain injury resulting from jaundice. A 2004 evidence review concluded that conventional phototherapy can reduce the risk of high bilirubin, but high bilirubin alone cannot accurately predict the incidence of kernicterus.⁵³ More recent evidence shows the N.N.T. is not uniform for all newborns, but depends on a number of factors. The N.N.T. to prevent a single case of high bilirubin for the average boy was 222 and for the average girl, 339.²⁶ But this number ranges from 10 to 3,041 depending on the neonate's sex, age at

treatment and gestational age at birth. The time of treatment matters in the control of bilirubin levels and the prevention of kernicterus, a brain dysfunction caused by extremely high bilirubin; phototherapy must be prompt to prevent morbidity.

Accepting that phototherapy, in general, is an effective treatment, we now examine the effectiveness of Brilliance in particular. Brilliance's effectiveness can only be approximated because field trials with human subjects have not yet been conducted. We do so by comparing Brilliance's technical specifications to expert guidelines, and reviewing internal product testing data and external certifications.

For a phototherapy device to be effective, the American Academy of Pediatrics (A.A.P.) guidelines state that it must emit light within the bilirubin absorption spectrum; reach a peak emission of 450 ± 20 nm; have an irradiance level ≥ 30 $\mu\text{W}/\text{cm}^2/\text{nm}$; and cover as much of the newborn infant's body surface as possible.⁵⁴ According to technical specifications for Brilliance Classic and Brilliance Pro, both models' irradiance footprints are >45 $\mu\text{W}/\text{cm}^2/\text{nm}$, which surpasses the A.A.P. intensive phototherapy standard of ≥ 30 $\text{mW}/\text{cm}^2/\text{nm}$. Peak wavelength (450-465 nm) also falls within the recommended emissions spectrum (430-490 nm). Both Brilliance models' irradiance footprints are designed to cover one horizontal body surface plane.¹³ Benchtop tests confirm that Brilliance Classic and the enhanced version, Brilliance Pro, both perform to their technical specifications.^{55,56}

Both Brilliance Classic and Brilliance Pro comply with European Union directives and regulations required for C.E. marking of medical devices.^{13,57} This allows D-Rev to market and sell the device in the European Union. Brilliance Pro has also been validated by third-party evaluator Thermal, Electrical, Mechanical, Photometric and Optical (TEMPO) Services, which conducted a luminosity test that found Brilliance Pro's peak wavelength of 451 nm fell within the recommended values.⁵⁸

In sum, in the absence of lab tests involving human subjects, the efficacy of Brilliance is established by how well its technical specifications conform to expert guidelines; whether those technical specifications are borne out in internal product testing; and how well it performs in external certification processes. Because the mechanics of Brilliance are relatively straightforward, Brilliance should theoretically deliver similar effects when deployed in clinical settings.

However, there are other factors besides the mechanics of the device itself that influence effectiveness, such as correct use of the device by clinicians and adequate supporting infrastructure in clinics.

In 2014, D-Rev participated in an independent field study of 33 hospitals in India with 53 Brilliance units among them. The study found generally poor quality of implementation.²⁴

Almost every Brilliance unit observed was raised to a height greater than the recommended 35 cm above the infant. Raising the lamp height dilutes the light reaching the patient's skin, with uncertain effects for treatment efficacy. To mitigate such misuse, both Brilliance Classic and Brilliance Pro were designed to be effective even if lamp leads are raised 10 cm higher than the recommended height.

A few smaller hospitals in poorer regions were also found to rely on clinical (i.e. visual) diagnosis rather than serum bilirubin blood tests to diagnose jaundice. At a public hospital in Thrissur, Kerala, doctors purposefully over-treat babies two or three times longer than in other hospitals because their lab cannot be relied upon to give accurate bilirubin readings.¹² Over-treatment may increase the risk and intensity of harmful side effects to the baby (and mother), such as prolonged mother-newborn separation and its effects on bonding and anxiety, and retinal damage.⁵⁹ Indeed, the 2014 field study found that although every infant observed had some eye covering, almost all had moved it out of place, increasing the exposure of high-intensity light to the retina.²⁴

In a public hospital in Alappuzha, Kerala, doctors estimated that 75 percent of the time, they treat two newborns at once with one Brilliance because of excessive demand. This results in an increased risk of infection, particularly from respiratory and umbilical cord infections that are transmitted through skin-to-skin contact, and possible exposure to too little healing light for each baby.^{24,60}

Through its own field work, D-Rev has found that cultural norms and misinformation can stand in the way of correct treatment, though cases are rare in hospital settings. For example, Chinese parents and grandparents sometimes worry about their child's future reproductive health and want to cover the newborn during phototherapy. In Burma, infants are wrapped in a blanket to protect their soul, which impedes accurate diagnosis and treatment of jaundice.⁶¹

Some of the upgrades incorporated into Brilliance Pro could reduce the potential for incorrect use. In the new 2015 model, D-Rev included an accelerometer to ensure consistent exposure even when the device is tilted. And while Brilliance Classic remains effective if its lamp head is set 10 cm higher than the recommended treatment height, Brilliance Pro is still effective 20 cm over its recommended treatment height. D-Rev also added an affordable light meter, to be purchased separately, so that doctors can confirm that the newborns are receiving the appropriate dose of light.⁶² Based on sales and installation data received from D-Rev,⁶³ we note that Brilliance Pro has by no means replaced Brilliance Classic and that some customers have elected not to buy the light meter.⁶⁴

There is much room for user error in the administration of Brilliance phototherapy. The most important issues are: incorrect lamp height; poor diagnostic practices; simultaneous treatment of multiple babies; inadequate skin exposure rooted in cultural practices; and an increased risk of side effects such as retinal damage due to improper eye protection and extended treatment time. D-Rev has tried to address some sources of improper use with user-centered design, exemplified by Brilliance Pro. But there remain serious concerns of improper use that are out of D-Rev's immediate control as a device company. Nevertheless, these concerns need to be accounted for in the algorithm for impact.

D-Rev also needs to improve on its study of how Brilliance is used in the field. D-Rev extrapolates how many newborns have been treated by combining sales and installation data from the manufacturer, Phoenix, with a study of how 33 hospitals used Brilliance in 2014.^{24,38} Layered on top of this is D-Rev's assumption about counterfactual access to phototherapy, which is based on surveys of a small sample of health facilities in Nigeria and India in 2010.^{38,65} Using this data, D-Rev assumes that 96 percent of both public hospitals and private, rural hospitals in low-income countries would otherwise not have access to effective phototherapy. That figure is 80 percent for private, urban hospitals in low-income countries. These assumptions are not air-tight: information could be outdated if conditions have improved, and samples are not statistically representative of the population D-Rev actually serves now. An impact algorithm should be more firmly rooted in up-to-date, credible data from the field.

The Rwandan Paediatric Association and University of California, Merced, are currently running a stepped-wedge cluster-randomized study testing 106 Brilliance units in 46 hospitals in Rwanda, in partnership with Child Relief International and the Ministry of Health of Rwanda.⁶⁶ The third-party study will measure peak bilirubin level in newborns diagnosed with jaundice in three clusters of hospitals tracked over four periods. In the first (baseline) period, all three clusters will not have access to Brilliance. In the second period, cluster A (16 hospitals) will receive Brilliance, while the two remaining clusters continue to have no Brilliance. Three months later, in the third period, cluster B (15 hospitals) will join cluster A in having access to Brilliance. After another three months, in period four, cluster C (15 hospitals) will finally also receive Brilliance. A pre-analysis plan is publicly available in the American Economic Association's registry.⁶⁷

Every public hospital in Rwanda determined to have the capacity to use Brilliance will be included in the study. However, because only 46 meet that requirement, the research team is unable to use their ideal experimental design, a randomized controlled trial. Given the small sample size, a stepped-wedge design is an appropriate substitute. It enables the study to achieve higher statistical power than a parallel-group design with the same sample size because the clusters act as their own controls, and the effect of Brilliance can

therefore be estimated from both between- and within-cluster comparisons. Tracking some clusters over multiple periods also allows the study's authors to model and control for the effects of time. The study's authors expect intervention effects will be large enough that sample size/statistical power will not be a problem.⁶⁶

TARGETING FOR BRILLIANCE

The target market for Brilliance is poor patients served by resource-limited referral facilities. Referral facilities are higher-acuity medical facilities to which patients are referred, as opposed to small rural clinics and micro-hospitals that may not have the trained staff, equipment and supporting infrastructure for phototherapy treatment. It was for this reason that D-Rev discontinued Comet, its phototherapy device intended for rural facilities.⁶⁸ D-Rev has since marketed Brilliance solely to hospitals with reliable electrical power, laboratories and neonatal intensive care units.

As of the end of 2016, Brilliance has been sold in 44 countries: Bahrain, Bangladesh, Belgium, Colombia, Côte d'Ivoire, Ecuador, Germany, Ghana, Guatemala, Guyana, Haiti, India, Indonesia, Iraq, Jamaica, Jordan, Kenya, Kosovo, Lebanon, Liberia, Libya, Malawi, Malaysia, Morocco, Myanmar, Nepal, Nigeria, Oman, Pakistan, Peru, the Philippines, Rwanda, Sierra Leone, South Africa, Syria, Tanzania, Thailand, Togo, Tunisia, Turkey, Uganda, the United Arab Emirates, Vietnam and Zimbabwe.²⁰ Approximately 90 percent of the 1,377 installed units of Brilliance Classic and Brilliance Pro went to urban hospitals and 80 percent to private hospitals.⁶⁹

D-Rev targets low-resource medical facilities as a way of reaching poor patients. D-Rev visits a sample of medical facilities using Brilliance, but often only those that are convenient to visit.⁷⁰ D-Rev also analyzes sales and installation data, submitted monthly by Phoenix, that show the addresses and facility types (private or public; rural or urban) where units have been installed. Both the field visits and data from Phoenix allow D-Rev to infer whether units are reaching low-resource facilities.⁷¹

Overall, the high proportion of units distributed to urban and private hospitals prompts some concern that Brilliance may not be reaching the poorest patients or clinics. The lack of demographic data collected directly from patients or clinics limits D-Rev's ability to allay this concern and conclusively demonstrate targeting effectiveness.

ReMotion Knee

The ReMotion Knee is an effective therapy for transfemoral amputees. The G.B.D. reference data estimate the value of a lower-limb prosthesis is about one-seventh of a DALY. In other words, if a lower-limb prosthesis worked for seven years, that would be equivalent to extending a patient's life by one year. No comparable estimates have been published in quality-adjusted life years (QALYs), a subjective measure of how effective patients find the treatment. The ReMotion Knee does not yet have strong evidence that it improves patient life to the aforementioned degree: the recent ReMotion field trial did not measure patients' utility using a standard quality-of-life instrument. But if we assume the G.B.D. disability weights can be applied, the 267 Knees fitted in 2015 would avert 28 DALYs over their device lifetime. D-Rev has fulfilled laboratory requirements for lower-limb prostheses with standards-setting bodies. Its recent field trial studied the mechanical performance of ReMotion, patient satisfaction, and counterfactual access to comparable lower-limb prostheses of 88 amputees at follow-up, but study size and research design limit the ability to derive an estimate of impact in DALYs averted or QALYs gained.

EFFECTIVENESS OF REMOTION KNEE

The medical literature indicates that prostheses increase the quality of life of amputees. According to Sincha et al.'s survey of 605 adult amputees in Mumbai, India, using a prosthesis increases physical quality of life scores by 20.059 out of 100 possible points ($p < 0.001$) and mental quality of life scores by 9.543 ($p < 0.01$), according to RAND's Short-Form Survey on quality of life. Meanwhile, the common alternative to a prosthesis, an assistive device such as a cane or crutches, decreases physical and mental quality of life scores by 8.768 ($p < 0.05$) and 9.926 points ($p < 0.001$), respectively.⁷²

Whether the ReMotion Knee, in particular, can be considered an effective prosthesis depends on how it performs in lab and field tests and against quality standards.

The ReMotion Knee complies with I.S.O. 10328, the internationally recognized standard that specifies procedures for strength tests on lower-limb prosthetic devices and structures.¹⁶ The ReMotion Knee fulfills the requirements of the European Union's Conformité Européene (C.E.) Medical Devices Directive 93/42/EEC, has been registered with the U.S. Food and Drug Administration (F.D.A.), and recently passed an F.D.A. inspection.^{73,74}

The ReMotion Knee fared well in a recent field trial of 143 amputees, of whom 88 were successfully reached for a follow-up survey six months after fitting.³⁷ 100 percent of the 88 respondents reported no mechanical failures; 90 percent were still wearing their

prosthetic knees at follow-up; and 84 percent were “satisfied” or “very satisfied” with ReMotion. At fitting, 57 percent of the original 143 amputees would not have had access to an effective prosthesis without ReMotion. At follow-up, that figure was 56 percent of the 88 respondents.

Importantly, D-Rev’s field trial did not measure quality of life along a recognized scale. It is not possible to transform D-Rev’s self-reported patient satisfaction, measured on a simple three-point Likert scale, to a standardized quality of life score like RAND’s Short-Form Survey. It is therefore unclear whether the ReMotion Knee is effective at improving the quality of life of amputees. In addition, the small sample size limits statistical power and the ability to detect the true effects of ReMotion.

We note that D-Rev and its clinical partner B.M.V.S.S. have both reported that collecting follow-up data is difficult because patients do not have any incentive to return to the clinic for the survey or respond to clinicians’ phone calls if they are satisfied with their ReMotion Knees.^{75,76} The 88 patients who returned for a follow-up survey may have been the most dissatisfied patients, therefore underestimating patient satisfaction of the original sample of 143.

D-Rev attempts to measure counterfactual access to a polycentric prosthesis such as ReMotion. Patients are considered to have otherwise had no access to a polycentric prosthesis if they self-report using an inferior (non-modular or exoskeletal) prosthetic, not being able to afford one, or being unaware of government prosthetics services.⁷⁷ This is a reasonable methodology. Patients were informed before being surveyed that they would be receiving a ReMotion Knee, so they should have had no reason to falsify their counterfactual access status to improve their chances of receiving ReMotion. However, it is unclear how B.M.V.S.S. chose patients to receive the ReMotion Knee. If selection was non-random, the 57 percent estimate would not be an accurate representation of counterfactual access.

D-Rev intends to sell ReMotion only when it can assure that clinicians correctly fit, and amputees correctly use, the prosthesis. First, D-Rev requires facilities that wish to purchase ReMotion to demonstrate they have a technician trained at the International Society for Prosthetics and Orthotics (I.S.P.O.) Category II level (i.e. an orthopedic technologist with further education and three years of formal training.)⁷⁸ D-Rev also seeks confirmation from an expert clinician at the facility that ReMotion is in fact what they want for their practice, even in cases where it is not the clinician but a procurement officer negotiating the sale with D-Rev.⁷¹ Once eligible facilities receive ReMotion, D-Rev requires that only trained prosthetists perform the fittings, including custom-molding the socket to fit the patient and assembling the knee with other components.⁷⁹ In addition, prosthetists

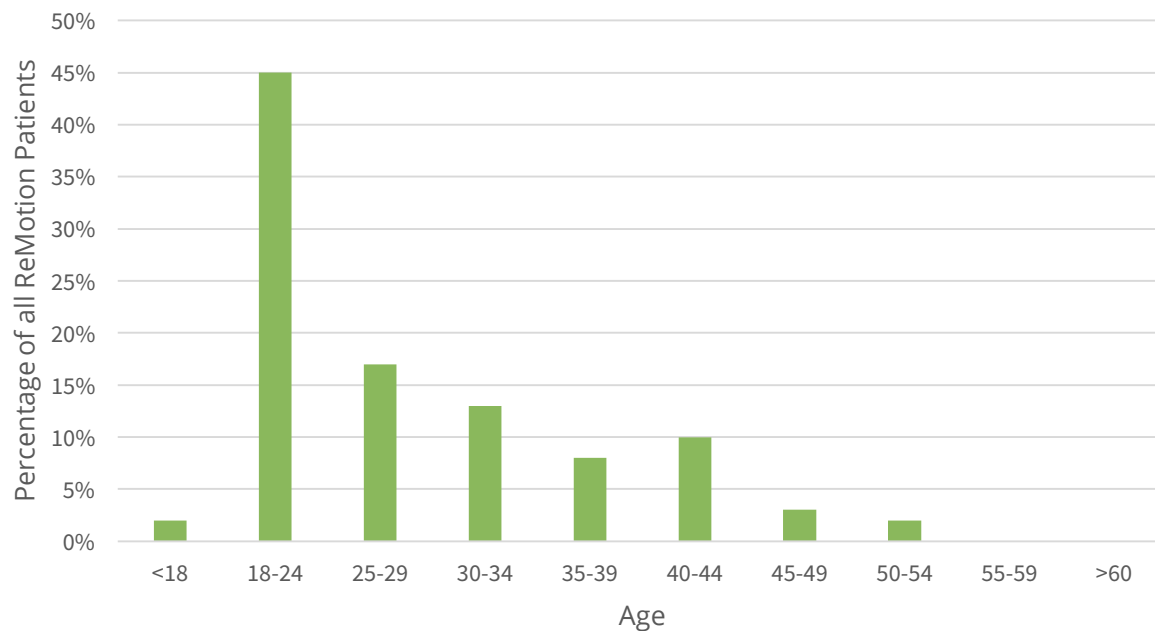
must indicate on D-Rev's survey the severity of medial-lateral play, pylon rotation and any other malfunctions, which prompts them to pay special attention to the way the knee is being fit. Given these requirements, it is likely that the ReMotion Knee is being fitted correctly by clinicians; but time will tell.

TARGETING FOR REMOTION KNEE

D-Rev targets amputees aged 18 to 60 years served by low-resource clinics.⁷⁶

The age distribution of the 143 patients fitted with ReMotion so far (as part of the 2016 field trial with B.M.V.S.S.) is illustrated below and demonstrates that D-Rev has been successful at targeting patients within this age range.⁷⁷

Figure 4. Age Distribution of ReMotion Patients



Field trials only took place in low-resource clinics, and on patients who independently sought care at those clinics^{80,81} Based on D-Rev's baseline data from the field trial with B.M.V.S.S., the average monthly income of the 141 respondents was approximately \$260 P.P.P.⁷⁷ In comparison, the average per capita monthly earnings in India was about \$510 P.P.P. in 2012.⁸² By these measures, D-Rev succeeded in reaching poor patients served by low-resource clinics.

D-Rev relies on prosthesis clinics in India to reach its target population. Clinic partners like Mukti Foundation⁸³ and B.M.V.S.S. provide prostheses and related services free-of-charge, and also run limb fitting and rehabilitation camps for patients who may not be aware of or

have the means to travel to their permanent clinics. According to D-Rev's Director of Impact, as a general rule, ReMotion actively seeks out partners whose mission is to serve the poor.⁷¹ It is likely these clinic partners have a good understanding of local poverty and therefore enable D-Rev to reach its target population.

QUALITY OF MONITORING SYSTEMS

WHY WE RATE

The quality of monitoring systems rating captures how well the nonprofit uses data to deliver a high-quality program. Nonprofits with strong monitoring systems use data to identify and correct problems.

HOW WE RATE

We rate the quality of systems the nonprofit uses to monitor delivery:

- **Activity:** to track program activities and outputs delivered
- **Targeting:** to identify beneficiaries to receive the program
- **Engagement:** to track if beneficiaries are taking up the program
- **Feedback:** to understand how participants view the program
- **Outcomes:** to measure changes in beneficiary outcomes

Each data system is assessed to determine if it meets the following criteria:

- **Credible:** Collect high quality data and analyze them accurately.
- **Actionable:** Commit to act on the data you collect.
- **Responsible:** Ensure the benefits of data collection outweigh the costs.
- **Transportable:** Collect data that fits with the nonprofit's theory of change

We score each type of monitoring system "Yes" or "No" on each criteria:

Criteria	Rating
Assessed "yes" on less than 25%	☆☆☆
Assessed "yes" on 25%-50%	★☆☆
Assessed "yes" on 50%-75%	★★☆☆
Assessed "yes" on more than 75%	★★★★

Rating

D-Rev has, on the whole, acceptable and often very good monitoring systems. Yet it has trouble ensuring that its systems are valid, reliable and unbiased – in other words, that its data credibly capture actual program delivery.

The two weakest aspects of D-Rev’s monitoring are: (1) collecting data from only those hospitals within easy reach (“convenience sampling”); and (2) reliance on outdated, potentially erroneous assumptions about devices in actual use. Overall, the quality of D-Rev’s monitoring systems gives a fair indication that D-Rev usually delivers a high-quality program to its participants.

Because D-Rev distributes services through other organizations, it faces tough tradeoffs with the design of monitoring systems. D-Rev can require that hospitals provide more information about the use of their devices, but that will tend to drive up the cost of devices to hospitals. D-Rev has considered the risks and decided that the additional benefit of collecting more data from hospitals does not justify the expense in device design, remote data collection and hospital staff time. Instead, D-Rev is allocating resources toward an impact evaluation.

Table 5. Quality of Monitoring Systems Rating Rubric

Criteria	Credible	Actionable	Responsible	Transportable
ACTIVITY DATA	✓		✓	✓
TARGETING DATA		✓	✓	
ENGAGEMENT DATA		✓	✓	✓
FEEDBACK DATA			✓	✓
OUTCOMES DATA		✓	✓	
CORRESPONDING RATING				★ ★ ☆

The main components of the monitoring systems used by D-Rev are:

1. **Targeting:** A scoring system allows D-Rev to focus research and development (R&D) on diseases and conditions that cause the most deaths and disabilities, and disproportionately affect developing countries relative to developed countries.

2. **Tracking the R&D process:** The R&D of every idea for a new device is documented in its own Design History File. Every idea progresses through five R&D phases and is tracked at phase review meetings. Benchtop and field tests are documented and reports are written to disseminate findings.
3. **Supply chain management:** D-Rev receives monthly sales and installation data from Brilliance manufacturer Phoenix, and tracks sales and distribution for the ReMotion Knee in-house using customer relationship management (C.R.M.) software.
4. **Field visits:** D-Rev staff conduct field visits both during the R&D phase, to inform new product development and validate assumptions, and after products are put on the market, to gather engagement, feedback and outcomes data.
5. **Baseline and follow-up surveys:** Surveys are administered to all ReMotion Knee field trial participants at their prosthesis fitting and six months later. Once the ReMotion Knee is on the market in August 2017, D-Rev will continue to survey a portion of patients at baseline and follow-up.
6. **Monitoring device performance:** All devices undergo monitoring of technical performance, including complaint tracking and resolution, as required by the International Organization for Standardization (I.S.O.), the U.S. Food and Drug Administration and Conformité Européene (C.E.) Medical Devices Directive. Phoenix and D-Rev manage these activities for Brilliance and ReMotion Knee, respectively.

Activities

STRENGTHS

D-Rev has credible systems for collecting data on its activities, and has demonstrated the willingness and ability to act based on that data.ⁱ Data collection is done responsibly, imposing a small burden on participants and a necessarily high burden on staff, who must ensure products are not deficient in quality. Human subjects are also appropriately protected during data collection. D-Rev is transparent about its activities to the public,

ⁱ The impact audit assesses monitoring systems using the CART Principles: credible, actionable, responsible and transportable data. The CART Principles are the heart of the Goldilocks Toolkit for Right Fit Monitoring and Evaluation, and they can be applied to all phases from evaluation design to implementation.¹⁰⁴ *Credible* monitoring systems “collect high quality data and analyze them accurately.” *Actionable* refers to a commitment “to act on the data you collect.” *Responsible* monitoring “ensures the benefits of data collection outweigh the costs.” *Transportable* data “generate knowledge for other programs.”

most notably sharing on its website frequently-updated data on device installations and publishing blog posts that offer insight into its work in the lab and the field.

WEAKNESSES

D-Rev needs actionable data about hospitals using Brilliance. As part of the R&D process, D-Rev conducts field work to verify that: clinical personnel would likely be present for diagnosis and therapy; laboratory facilities are adequate; clinical personnel have the requisite knowledge and skills; and that clinical facilities have the non-laboratory infrastructure to support the devices, such as electricity. However, D-Rev conducts this field work on just a small percentage of the total facilities that will potentially receive Brilliance units. In addition, D-Rev only follows up with a small percentage of facilities after they have installed Brilliance units.⁸⁴ D-Rev's field work both before and after installation is not adequate to confidently verify the assumption that all facilities with Brilliance units have the staffing and infrastructure necessary to make the best use of Brilliance. This is corroborated by field work contracted by D-Rev in 2014 in India, which showed adherence to phototherapy treatment protocols was poor.²⁴

Targeting

STRENGTHS

D-Rev's targeting data are demonstrably and routinely used as the basis for deciding which diseases and devices to pursue. D-Rev is also responsible in its collection of targeting data, for instance by making sure ReMotion patients give informed consent before answering surveys.

WEAKNESSES

D-Rev should collect more information on the patient population it is ultimately reaching. D-Rev's targeting data collection is a rough composite of several processes: identifying diseases and conditions that disproportionately afflict the poor; conducting informal field visits; and analyzing data from distribution partners about the population that is being served. But the informal field work that D-Rev conducts does not credibly verify that products are reaching underserved populations. Observational notes are taken for each field visit, but the information ultimately recorded and escalated for management attention is highly subjective, based on the opinion of whoever conducts the visit.^{85,86} D-Rev should conduct more systematic field visits and target those visits at a random sample of clinics. Though D-Rev has pilot-tested ways to collect patient

information without overburdening health facilities, for instance using SMS, it has yet to find a viable solution. Incentivizing clinics and customers to provide that information willingly remains a challenge. In addition, D-Rev should more closely analyze the sales and installation data submitted by Phoenix to infer whether targeting has been successful.

D-Rev does not describe in public communications its targeting strategy or the general profile of its target population. D-Rev broadly states that it targets "under-served populations" in the "developing world" and "low-resource settings," and lists the countries in which its devices have been installed (for instance, see "[About](#)"). But D-Rev could specify more precisely, in public communications, the level of unmet need of its target population and how that level is measured. In addition, it is unclear to public audiences how D-Rev's sales strategy enables it to reach its target population. For instance, D-Rev could be more transparent that it prioritizes referral facilities (regional-level facilities to which patients get referred, usually from more informal, rural clinics) for Brilliance⁸⁷ and that prosthesis clinics must meet certain criteria to receive ReMotion Knees.⁷¹

Engagement

STRENGTHS

D-Rev's engagement data systems are generally excellent, and satisfy criteria for being actionable, responsible and transportable. Notably, all Brilliance devices have a built-in therapy timer, which displays the number of hours lights have been turned on. This is an unbiased and reliable measure of treatment time, from which D-Rev can extrapolate the number of babies its devices have treated.

WEAKNESSES

D-Rev should manage patient incentives across all clinics in order to avoid differential survey attrition and ensure an unbiased measure of engagement. D-Rev faces difficulty gathering the endline data necessary to prove compliance with the ReMotion Knee due to the long distances and opportunity cost patients face traveling to clinics for the endline survey and check-up. According to one clinician, if patients' Knees are functioning well, they lack the incentive to return to the clinic just for the survey. Hence, during the 2016 field trials, her clinic offered a travel stipend to defray costs, a nominal incentive for participation, and the option to conduct follow-up surveys over the phone.⁷⁵

D-Rev has limited information on where, when and to whom Brilliance units are installed, especially outside of India. Distributors (who purchase Brilliance units from

Phoenix) do not always keep good records and have sometimes been wary of external parties requesting such information. There have been cases where D-Rev has had to intervene because a major tenderer outside India failed to produce information about installation.⁸⁸ And since India-based Phoenix has the best visibility into India-based distributors, installation data from Phoenix may systematically not cover other countries accurately and D-Rev could risk acting on and reporting erroneous engagement data. However, Phoenix has, in some cases, started to formally require purchasers to report distribution information.⁸⁸

The biggest concern about systematic error in D-Rev's engagement data is the way it estimates Brilliance usage data. First, D-Rev uses an algorithm that calculates usage data from (1) installation data from Phoenix and (2) field observations of average device usage in 2014. But the 2014 field observations have not been updated and continue to be the basis of the algorithm today.³⁸ Second, the field visits D-Rev conducts to collect a portion of usage data first-hand are opportunistic and unsystematic in nature. D-Rev uses convenience sampling for field visits, meaning D-Rev and its partners only visit those facilities that are geographically and logistically convenient to visit.⁸⁴ This introduces bias in the sample for usage data: it may be that the facilities D-Rev visits, which are typically located close to one another and close to where D-Rev staff are already travelling to, are systematically more (or less) likely to be using Brilliance devices with more (or less) frequency and intensity.

Feedback

STRENGTHS

Feedback data systems at D-Rev are responsible, in that they minimize the burden of data collection and reporting and they respect patients' rights to consent and privacy. They are also transportable, in that they relate to and support D-Rev's theory of change and are described publicly on D-Rev's blog. Perhaps most illustrative of D-Rev's use of feedback is its commitment to user-centered design and systematic resolution of complaints. For instance, end-user feedback about Brilliance Classic directly resulted in the enhanced features of Brilliance Pro.

WEAKNESSES

D-Rev should ensure feedback are collected from a representative sample of clinics. D-Rev conducts ad hoc field visits, interviewing medical personnel at a very small number of

facilities that use Brilliance and that are logistically convenient to visit, thereby introducing risk of systematic error into its data.

D-Rev should use feedback from Phoenix to ensure distribution partners honor D-Rev's terms of agreement with respect to royalties, licensing and pricing. Though this is certainly not the norm, there is anecdotal evidence that distributors have substantially marked up the price of Brilliance to consumers.⁸⁷ Phoenix monitors end-user prices to the extent possible and relays this as feedback to D-Rev, but the information captured is not complete, particularly outside of India, where Phoenix has less direct control over supply chains.⁴⁰ D-Rev should work with Phoenix to both proactively enforce terms of agreement with distributors and reactively track end-user prices charged by distributors.

Outcomes

STRENGTHS

Over the last year, D-Rev has invested in strengthening its internal reporting and decision-making processes, resulting in actionable outcomes data systems. As with all other forms of data that D-Rev collects, outcomes data are also collected responsibly, with minimal burdens imposed on staff and patients and demonstrated sensitivity to data ethics issues. D-Rev has also made the responsible choice to publicly report only the number of devices sold and subsequently verified as installed, rather than simply the number of devices sold. D-Rev believes that the number of devices sold and number of devices installed should in fact be comparable, given that devices are purchased by – not donated to – willing buyers who have entered into the transaction voluntarily. But since there can be substantial lag time before a distributor confirms to D-Rev that a device has been installed, D-Rev has conservatively chosen to report the lower of the two figures: devices with confirmed installations.

WEAKNESSES

D-Rev uses an indirect method for arriving at the number of babies treated with Brilliance. D-Rev uses an algorithm based on Brilliance sales and installation data and a set of assumptions informed by field work conducted in 2014.^{23,24,75} The assumptions are: average (i) percentage of the time that Brilliance units are left on without the baby being treated; (ii) percentage of time during phototherapy treatment that a baby is removed from lights; (iii) hours a day that a Brilliance unit is in use; and (iv) hours required to treat each baby.³⁸

D-Rev's estimate of the impact of its phototherapy device suffers from three problems. First, sales are expanding beyond India, but all of the observations in the 2014 report were from Indian hospitals, where virtually all Brilliance devices were then installed. D-Rev is actively collecting data from at least three other countries, which, when combined with data from India, represent over 90 percent of sales; but this data was not yet available at the time of the audit. Second, the algorithm uses recorded installation dates to calculate days in use, but the report found installation dates can be misleading for public-tender cases, where facilities may install devices months after a central purchasing authority receives them.²⁴ Third, Phoenix's method for classifying facilities as rural and urban has not been validated and has been found to be unreliable.²⁴

In sum, D-Rev would benefit from updating its assumptions with more frequent and well-sampled field work.²⁴ Indeed, D-Rev itself found important discrepancies between actual and imputed data on device usage.²⁴ D-Rev speculated the discrepancies were due to inaccurate assumptions made based on past field work, emphasizing "how critical it is to collect real data as a check on assumptions we use in current algorithm for calculating impact."

D-Rev's outcomes data are not adequate to capture the true change in patient outcomes that should occur as a result of its intervention. D-Rev continues to encounter the tension between collecting better data on patient outcomes and incurring the high cost of data collection.⁷⁵ For instance, D-Rev considered using mobile-data chips (3G) to report device usage automatically, which would vastly improve the collection of Brilliance usage data, but would also require a substantial capital investment.⁸⁹ Requiring customers and medical personnel to participate in reporting could also improve data quality, but would require incentives of some kind; and it might turn customers away. Such costly investments in monitoring systems could jeopardize the affordability of D-Rev's products if D-Rev passes on costs to the customer. But if D-Rev is able to spare end-users the additional cost, it would be well worth the investment to boost the quality of D-Rev's outcomes data.

LEARNING AND ITERATION

WHY WE RATE

Learning and iteration captures how a nonprofit learns about its own model and makes decisions to change its model. We reward nonprofits that are using high quality data to learn about areas for improvement, and then acts on that data to iterate its model systematically and periodically. Such nonprofits are more likely to maintain and increase the impact of their core programs, and are likely to be more resilient and responsive to shocks and other changes within the nonprofit and the environment in which it works.

HOW WE RATE

We rate how well the nonprofit uses data to learn what does and does not work and then appropriately iterates its model.

We rate nonprofits at **all stages** against the following criteria:

Criteria	Finding
No iteration or arbitrary iterations in model	☆☆☆
Nonprofit iterates its model based on data that are low quality	★☆☆
Nonprofit iterates its model based on data that are high quality	★★☆
Nonprofit systematically and periodically iterates its model based on data that are high quality	★★★

Rating

D-Rev has an exceptional research and development (R&D) process. Over the last three years, D-Rev considered four new ideas (iterations) for its portfolio of devices. It adopted three. Three of the iterations were tested in the lab, in the field or both.

Decisions to implement iterations were supported by high-quality data. In most cases, decisions were made systematically, following a Plan-Do-Check-Act learning cycle. Ideas for iteration were sourced, tested, analyzed and implemented, in that order. The exception was an iteration named “Comet,” which was not sourced appropriately but based solely on certain unchecked assumptions. But D-Rev's R&D process has matured considerably since Comet was first tested in 2013-2014. Finally, D-Rev satisfies the requirement that it iterate periodically, as D-Rev brainstorms and reviews iterations on a regular basis.

Table 6. Learning and Iteration Rating Rubric

Criteria	Finding
ITERATION IS BASED ON DATA	Yes
DATA ARE OF HIGH QUALITY	Yes
ITERATION IS SYSTEMATIC AND PERIODIC	Yes
CORRESPONDING RATING	★ ★ ★

Products

REMOTION KNEE

The ReMotion Knee is the next-generation version of the original 2008 JaipurKnee. Since D-Rev acquired the intellectual property of JaipurKnee in 2011, it has made notable changes to the original design: rounded edges, injection molding for mass production, and certain hardware components of the knee.⁹⁰ These improvements were motivated by user feedback during prototyping and field trials.^{76,91} The latest version of the ReMotion Knee was launched in 2015, taken off the market seven months later to improve on some mechanical issues, and then relaunched globally in August 2017. The original JaipurKnee is

still manufactured and distributed today by D-Rev partner Bhagwan Mahaveer Viklang Sahayata Samiti (B.M.V.S.S.).

The ReMotion Knee has undergone its first phase of testing. Data are still being collected for the second phase. For both phases, D-Rev surveyed patients at baseline (just before being fitted with the prosthesis) and follow-up (six months after fitting). The first phase measured patient compliance and satisfaction. Only in the second phase of testing did D-Rev estimate counterfactual impact by measuring the number of amputees fitted with ReMotion *who would otherwise not have had access to an effective prosthesis*.⁹² This includes amputees who had been using non-modular or exoskeletal prostheses prior to ReMotion and were unable afford an effective prosthesis and amputees who were not aware of basic prosthetics services provided by the Indian government. D-Rev found 57 percent of the 143 patients fitted with ReMotion would otherwise not have had access to effective prostheses.⁷⁷

Based on this figure and preliminary data that indicate promising compliance and satisfaction rates,⁸⁰ D-Rev decided to begin preparing for ReMotion relaunch in 2017. Multiple staff interviews, blog posts and the new ReMotion Knee microsite all indicate D-Rev made detailed preparations for the launch.^{10,11,91}

COMET

Comet was a compact, low-cost phototherapy device intended for rural clinics and micro-hospitals far away from urban referral centers. After studying Comet in 2013-2014, D-Rev ultimately found that phototherapy devices are not viable for rural clinics, which lack inpatient care, the ability to treat comorbidities, the ability to diagnose jaundice, reliable power and adequate personnel training.⁶⁸

After Comet was benchtop-tested, D-Rev installed 13 prototype Comet devices in clinics in India, Kenya and Nepal. From October 2013 to March 2014, the prototypes were used to treat 137 newborns, 117 of whom D-Rev estimates would not have received effective jaundice treatment without Comet. This estimate is based on field studies D-Rev conducted in 2009 and 2012, which continue to form the basis of its current counterfactual impact algorithms for Brilliance.⁹³ However, the field test revealed considerable under-use of Comet. Of the 13 prototype units, six were not used at all, and the units were only turned on 16 percent of the days they were available for use.⁶⁸ When Comet *was* in use, it was in the larger clinics and hospitals and not the target rural areas for which Comet was designed. Overall, the test clearly showed that targeting for Comet was flawed: lack of access to effective phototherapy devices is not the only barrier that rural communities in developing countries face; rather, this population also lacks other

infrastructure and functioning systems necessary for phototherapy, such as a way to keep babies warm and a reliable power source. Accordingly, D-Rev decided to shutter the Comet initiative.

The idea for Comet germinated within the D-Rev team, rather than from monitoring data or evidence from elsewhere.¹⁰ D-Rev staff assumed that Comet would fill the gap in the market for phototherapy in rural clinics and micro-hospitals because it would be extremely affordable, occupy less space in small facilities, and be easy to set up without technicians and advanced medical professionals. But D-Rev's misstep was launching field trials without first validating this assumption, for instance through interviews with in-country key informants.

DARKWING

Darkwing was a compact phototherapy device with a smaller shipping-container footprint than Brilliance Classic/Pro and therefore cheaper to deliver. It was intended to increase product reach outside of India, especially in Sub-Saharan Africa and Southeast Asia. D-Rev explored the concept of Darkwing in 2014, but found that a number of assumptions behind it did not hold and decided not to pursue Darkwing further.¹⁰

Darkwing did not progress to the prototype-testing phase. Instead, the "iteration test" for Darkwing consisted of early-stage consultation with the design professionals at both D-Rev and manufacturing partner Phoenix. D-Rev presented the product concept at a design review meeting, which resulted in the invalidation of a number of key assumptions.^{94,95} First, international customers make decisions based on list prices and would likely not change procurement decisions because of a lower landed-cost. Second, the necessary design and engineering changes would drive up the bill of materials (BOM) cost and might therefore compromise D-Rev's commitment to low prices, introduce production inefficiencies at Phoenix, and actually render the device structurally unsound. As a result, D-Rev made the sensible decision not to pursue Darkwing.¹⁰

BRILLIANCE PRO

Brilliance Pro is a revision of Brilliance that includes an integrated light meter, a backlit LED screen, observation lights and SmartTiltⁱ technology.⁹⁶ Brilliance Pro has the same retail price as Brilliance Classic, but includes many technical and design improvements

ⁱ SmartTilt technology automatically adjust the strength of the light when the device head is tilted, keeping light strength constant throughout therapy.

based on feedback from doctors, patients, and the service engineers, sales staff and manufacturing leads at Phoenix.⁹⁷ Brilliance Pro was launched in January 2015.

D-Rev launched Brilliance Pro after prototyping and benchtop-testing the prototype in-house to verify design integrity,⁹⁸ temperature safety⁹⁹ and tensile safety.¹⁰⁰ D-Rev also partnered with a third-party evaluator, Cree's TEMPO Services, to verify that Brilliance Pro passed industry-standard tests specifically related to LED lighting.⁵⁸ Taken together, the in-house and third-party tests showed that Brilliance Pro prototypes passed the majority of product specification requirements and industry standards.¹⁰¹ D-Rev then worked with Phoenix to initiate mass production and orchestrate the market launch in January, 2015.

Product Design Process

D-Rev has a sophisticated R&D process that explores and selects ideas for iterations on an ongoing basis. Key staff participate are familiar with the products in the pipeline and participate in regular reviews.^{5,7,11} Every product or revision that enters the pipeline has a Design History File that documents its progress.⁷

D-Rev begins its product development cycle by generating a list of diseases. The diseases on the list have burdens that exceed 100 million DALYs in developing countries and are twice as large as corresponding disease burdens in developed countries, as measured by the 2010 Global Burden of Disease Study.¹⁰² This process is documented in spreadsheet form with input from key D-Rev decision-makers, and uses a scoring system to identify the diseases D-Rev should focus its R&D efforts on.^{4,7}

After diseases are selected, the R&D process unfolds in five phases: Concept, Early Design Development, Late Design Development, Design & Manufacturing Verification, and Sustaining & End of Life. At the end of each phase, the D-Rev team holds a phase review meeting, with key leaders present, to decide whether to move the iteration ahead to the next phase, cancel the iteration, or do further research and meet again.^{7,103}

More so than for many other nonprofits, D-Rev's future impact relies heavily on its ability to innovate. To this end, D-Rev has successfully built an R&D machine that is in constant motion and is meticulous enough to weed out interventions that are unfit for competitive markets and medical use. To achieve its strategic goal of becoming a portfolio "medtech" organization with a range of devices under its belt, D-Rev would do well to maintain and even scale up its excellent research and development.

BACK MATTER

Metadata

Table 7. Nonprofit Details

LEGAL NAME	D-Rev Design for the Other Ninety Percent
E.I.N.	26-0642778
WEBSITE	www.d-rev.org
CONTACT EMAIL	info@d-rev.org
ADDRESSES	Mailing and physical: 695 Minnesota Street, San Francisco, CA 94107

Table 8. Impact Audit Details

YEARS OF ANALYSIS	2013-2015
PUBLISHED	September 26, 2017
PERMALINK	www.impactm.org/a/d-rev/1
STANDARD	Version 0.3
ACTIVITIES	Evidence review, document and data review, senior management interviews, field staff interviews and key informant interviews.
AUDIT TEAM	Tamsin Chen and Ben Mazzotta
REVIEW TEAM	Elijah Goldberg and Michael Weinstein
CONFLICT DISCLOSURES	Kevin Starr, a member of ImpactMatters' board, leads Mulago Foundation, a funder of D-Rev.

Monitoring Systems Scoring

Table 9. Monitoring Systems Scoring Rubric

Criteria	Activity	Targeting	Engagement	Feedback	Outcomes
CREDIBLE					
VALID	✓	✓	✓	✓	
RELIABLE	✓		✓	✓	✓
UNBIASED	✓	✓			
ACTIONABLE					
READY	✓	✓	✓	✓	✓
RISKS AND ASSUMPTIONS		✓	✓		✓
COMMITMENT TO ACTION	✓	✓	✓	✓	✓
RESPONSIBLE					
MINIMIZES BURDEN	✓	✓	✓	✓	✓
ETHICS	✓	✓	✓	✓	✓
TRANSPORTABLE					
THEORY OF CHANGE	✓		✓	✓	
TRANSPARENCY	✓		✓	✓	✓
TOTAL PASS					40 / 50
CORRESPONDING RATING					★ ★ ☆

Glossary

A/B test

An A/B test compares the current version of the program to a modified version in order to test which version is more effective at changing engagement, outcomes or some other metric of interest. A/B tests do not have a pure control group and are not designed to test the overall impact of a program. Instead, they are intended to improve the design of a program by determining whether a nonprofit should modify its program or keep it as is.

Activity data

Activity data is a form of monitoring data that tracks program activities completed and outputs delivered. Activities are the day-to-day tasks an organization must undertake in order to provide a product or service. Each program activity has at least one output associated with it. Outputs are the products or services produced by the nonprofit.

Additive iteration

An additive iteration is a change to a nonprofit's program that adds a new component, as opposed to modifying an existing component or removing a component. When assessing how a nonprofit learns and iterates, an additive iteration has a lower burden to justify adoption if it meets three conditions: (1) it is unlikely to have a negative impact (but may have no impact), (2) is unlikely to reduce the impact of other components of the program and (3) does not significantly increase program costs.

Applicability

Applicability of evidence to a nonprofit's program includes two distinct concepts: quality and relevance. Quality captures the internal validity of the evidence: is the evidence free of factors that may bias the reported findings? Relevance captures the external validity of the study to the nonprofit's intervention: to what extent do we expect the intervention to generate similar impact as the findings observed in the study?

Attrition

Attrition refers to cases where members of a sample drop out between rounds of data collection. For instance, if a 100 people are surveyed at the beginning of the program but only 90 can be surveyed at the end of the program, the attrition rate is 10%. Attrition can be problematic if attrition from the sample is correlated with outcomes. For instance, when following up on a health intervention, those who are sick may be more difficult to find than those who are healthy. As a result, the reported results may be biased because they include outcomes for fewer sick individuals.

Average costs

Average costs are the total amount of money spent by the nonprofit divided by some unit of output or outcome. Average costs include costs that are fixed and not expected to increase as outputs or outcomes grow, such as salaries of senior managers. See also Marginal Costs.

Behavior change

Changes to patient behavior that are required in order for therapy to be effective. Devices that require behavior change are less likely to be implemented successfully than those that do not require behavior change.

Behavioral bias

A behavioral bias is any tendency that leads people to not make rational decisions given available information and their own preferences. Common behavioral biases include confirmation bias, where people weight facts that confirm their opinions higher than those that do not; loss aversion, where people value losses greater than equivalent gains; and availability bias, where people overestimate the likelihood of events based on how “available” they are in their memory. Many charitable interventions are designed (sometimes unintentionally) to help individuals correct these biases.

Bias

Bias is a non-random error in a statistical estimate. Whenever estimates are based on a sample from a larger population, there will be random error in that estimate: no two samples will produce exactly the same estimates. An estimate is biased when those errors lead it to be consistently above or below the true value that is being estimated.

Cluster-randomized

A study is cluster-randomized if the randomization was performed at the group (or cluster) level, instead of the individual participant level. Types of clusters include, but are not limited to, villages, schools and districts. See also Randomized Controlled Trial.

Control group

A control group is a group of participants who did not receive the intervention. Control groups enable nonprofits and researchers to compare what happened to beneficiaries in their program to what might have happened if they were not in the program. See also Treatment Group.

Convenience sampling

Subjects are selected for inclusion in the study sample because they are conveniently available to the researcher. Subjects are not selected at random from the total population or population strata.

Counterfactual; counterfactual evidence

The counterfactual is what would have happened in the absence of a program or other event. Understanding the counterfactual is essential to understanding the impact of a program. Participant outcomes may change over time for many different reasons not related to the program. By comparing the difference between participant outcomes and counterfactual outcomes, the impact of a program can be estimated.

The counterfactual cannot be directly measured, as researchers cannot observe the same participant both participating and not participating in the program. However, it can be approximated by randomizing participants into an intervention group and a control group, and then comparing outcomes across the two different groups.

Credible, Actionable, Responsible and Transportable (CART)

The CART standard is a method for understanding the quality of monitoring systems. CART stands for:

- **Credible:** Monitoring systems are credible if they collect high-quality data that is analyzed accurately.
- **Actionable:** Monitoring systems are actionable if the nonprofit commits to act on the data that it collects.
- **Responsible:** Monitoring systems are responsible if the nonprofit minimizes the burden of data collection and collects data ethically.
- **Transportable:** Monitoring systems are transportable if the data collected is tied to the nonprofit's theory of change and is shared appropriately.

Design stage

A nonprofit at the design stage has a program model that is undergoing change.

Difference-in-differences

A statistical technique that compares the change over time in the outcome variable of the treatment group, to the change over time in the outcome variable of the control group. It may be used for multiple time periods and multiple groups. Common variations include "difference in difference" and "difference-in-differences."

Differential attrition

The characteristics of members who drop out of a sample differ systematically from those of members who do not drop out. In studies with a comparison group, it is also the difference in the rate of attrition between intervention and comparison groups.

Disability-adjusted life year (DALY)

A measure of one lost year of health life. The burden of disease in DALYs is the sum of years of life lost (Y.L.L.s) and years lived with disability (Y.L.D.s). See Murray CJ, Lopez AD, World Health Organization. The global burden of disease: a comprehensive assessment of mortality and disability from diseases, injuries, and risk factors in 1990 and projected to 2020: summary.

Discount rate

People tend to value benefits in the future less than benefits in the present, for three primary reasons. First, benefits today can be reinvested and generate some return. Second, the future is uncertain, and we are often uncertain if future benefits will actually materialize. Third, most people are impatient, and prefer immediate gratification over future gratification. A discount rate captures this by discounting or reducing future benefits compared to current benefits.

Economic significance

Refers to the magnitude of the treatment effect in practical terms. Economically significant results have a meaningful experience on the subjective experience of the beneficiaries, in that they are large enough to be noticed. Differs from statistical significance, which refers to the confidence with which a null hypothesis can be rejected.

Effect size

In statistics, the effect size refers to the ratio of the treatment effect to the standard deviation of the outcome variable. In other words, it is a normalized treatment effect, with the standard deviation of the outcome variable as the numeraire.

Engagement data

A form of monitoring data that tracks initial take-up of the program and how people interact with the product or service. For instance, if individuals are offered a savings account, engagement data might include how many people accept the offer and open a savings account, how many times people deposit and withdraw, how many times people check their balance and similar measures of how people interact with the product.

Enumerator

A person employed to collect data. Enumerators are often hired by survey firms to collect data on behalf of a study or nonprofit. Enumerators are often, but not always, independent of the program delivery staff.

External evidence

In an impact audit, external evidence includes studies – such as randomized controlled trials, quasi-experimental studies, laboratory results and systematic reviews – on interventions that are similar to the nonprofit’s intervention. The motivating theory behind using evidence from elsewhere is that there exists some true effect size for a specific intervention (or more realistically, a range of true effect sizes). If the same intervention has been measured elsewhere and shown to produce a particular effect – and that intervention has some true effect size – one should expect the same intervention, given a similar context and quality of implementation, to have a similar effect size (after accounting for random noise).

Externality

An externality is a consequence or effect of an activity that is not reflected in the cost of the goods or services exchanged. Externalities affect third parties, and those effects can either be positive or negative. Nonprofits often exist to correct externalities, such as pollution. Nonprofits can also themselves generate externalities, such as positive economic growth in a community when they provide services to some community members.

Feedback data

Feedback data is a form of monitoring data that gives information about the strengths and weaknesses of the program from participant or other stakeholder perspectives. Feedback data can provide valuable information about how to improve program design.

High quality

High-quality evidence under the GRADE rubric is the best scientific evidence that the program has its intended impact. Randomized designs are presumed to be in this category unless our analysts are concerned about flaws in the methodology or weak results.

Hyperbilirubinemia

Excess bilirubin (hyperbilirubinemia) is the main cause of jaundice. Bilirubin, which is responsible for the yellow color of jaundice, is a normal part of the pigment released from the breakdown of "used" red blood cells. ([Mayo Clinic](#))

Impact

Impact is a change in beneficiary outcomes attributable to a nonprofit's activities and outputs. See also Outcome Metrics; Outcomes.

Independent evaluator

An independent evaluator can include a research organization or academics engaged to analyze the impact of a program. Independent evaluators are not directly employed by the program, although they may be paid through program resources.

Internal evidence

Internal evidence includes all efforts by the nonprofit itself to evaluate the impact of its work. Internal evaluation can include anything from collecting outcomes before and after implementation to conducting a randomized controlled trial. It can also include independent evaluations of the nonprofit's own program.

Independent evaluations do not necessarily need to be conducted at an arm's length; the nonprofit is often involved in the design and analysis phase, and will be involved in executing the actual program itself and often in collecting data. However, to qualify as an independent validation, a third-party must have a substantial decision-making role in design and overall control over analysis of the evaluation.

Intervention

An "intervention" is what researchers study and nonprofits do. An intervention includes anything from a medical procedure to a conditional cash grant. ImpactMatters studies the intervention that a nonprofit implements, mapping that intervention to the evidence base out there on that particular intervention.

Iteration

A change to the design of a model component of sufficient importance that it likely changes the relationship between the component and subsequent steps in the nonprofit's theory of change.

Kernicterus

The syndrome that occurs if acute bilirubin encephalopathy causes permanent damage to the brain. ([Mayo Clinic](#))

Learning and iteration

Learning and Iteration is the section in the impact audit that assesses and provides a rating for the historical processes the nonprofit has used to determine changes to the design of its intervention. We rate how well the nonprofit uses data to learn what does and does not work, and then appropriately iterates on its model.

LED

Light-emitting diode; an electric light source with lower energy consumption and a longer lifetime than incandescent light sources.

Low quality

Low-quality evidence under the GRADE rubric is weak evidence of the impact of a program. Observational studies are presumed to be of low quality unless flaws are mitigated and the research shows very convincing results, such as with a large effect size and a clear dose-response curve.

Lower-limb prosthesis

An artificial leg fitted to an amputee.

Marginal costs

The incremental change in total cost due to increasing the quantity produced by one unit. In an impact audit, for example, marginal cost refers to the change in total cost incurred when one more participant is served in the nonprofit's program. See also Average Costs.

Market failure

A market failure is a situation in which the allocation of goods and services is not efficient. There exists another conceivable outcome where individuals may be better off without making anyone else worse off.

Medium quality

Medium-quality evidence under the GRADE framework has some flaws that might render estimates of impact inaccurate. Quasi-experimental designs are presumed to be in this category unless flaws are mitigated and results are convincing. Those designs can also be rated down to low quality if our analysts are concerned about the methodology or results.

Missing market

A missing market exists when there is demand for a good or service, but there is no available supply of this sought-after product. For example, the extreme poor face missing markets for financial services, such as microcredit, microsavings and microinsurance.

Monitoring systems

Monitoring systems are the means by which the nonprofit produces and uses data to ensure it is consistently delivering its program at high quality. Monitoring systems track every step required in the delivery of the intervention using five types of data: activity, targeting, engagement, feedback and outcomes data. In an impact audit, monitoring systems are assessed to determine if they fulfill the CART standard. See also CART.

Morbidity

Nonfatal outcomes associated with a disorder, such as acute illness or disability.

Mortality

Fatal outcomes associated with a disorder.

Multiple treatment arm randomized controlled trial (M.T.A.R.C.T.)

A randomized controlled trial that uses multiple treatment groups to simultaneously test variations of an intervention or disentangle effects of multi-component interventions. See also Randomized Controlled Trial.

Neonatal jaundice

Infant jaundice is a yellow discoloration in a newborn baby's skin and eyes. Infant jaundice occurs because the baby's blood contains an excess of bilirubin (bil-ih-ROO-bin), a yellow-colored pigment of red blood cells. ([Mayo Clinic](#))

Number needed to treat (N.N.T.)

The number of patients that must be treated in order to prevent one from suffering morbidity or mortality.

Outcome metrics; outcomes

Outcome metrics are a direct measure of the success of the program in addressing the underlying problem. For example, in a malaria control program, the number of households with sufficient insecticide-treated bednets would be a process metric and the rate of malaria infections in the zone would be a measure of outcomes. See also Process Metrics.

It is important to emphasize that change in outcome metrics is still not sufficient to document impact, since there is no counterfactual comparison. But the unit of measure of the outcome (malaria prevalence) is the same as the measure of impact, since the measure of impact is a simple arithmetic difference between the observed outcome and the estimated counterfactual outcome

Phototherapy

Newborns suffering from jaundice may be placed under special lighting that emits light in the blue-green spectrum. The light changes the shape and structure of bilirubin molecules in such a way that they can be excreted in the urine and stool. The light isn't an ultraviolet light, and a protective plastic shield filters out any ultraviolet light that may be emitted. ([Mayo Clinic](#))

Plan-Do-Study-Act

The Plan-Do-Study-Act cycle is a repetitive four-step model for carrying out change in an organization. In an impact audit, nonprofits are assessed on whether iteration ideas were sourced; tested; analyzed and summarized for decision-makers; and then accepted and implemented systematically. Also known as the Plan-Do-Check-Act cycle, Deming cycle and Shewhart cycle.

Polycentric prosthesis

An improved design of the prosthetic knee that is more stable and durable.

Pre-post comparison

Comparing the outcomes of a treatment group before and after receiving the intervention. The pre-intervention outcomes serve as a (poor-quality) estimated counterfactual. Synonyms: before-and-after comparison; reflexive comparison. See also Counterfactual.

Problem

In the context of an impact audit, the problem comprises a target population that suffers from an underlying market or government failure (referred to as the source of the problem), leading to a social inefficiency. See also Social Inefficiency.

Process metrics

Process metrics describe delivery of goods and services and observable behavior changes in the target population. See Outcome Metrics; Outcomes.

Prosthetic knee

An artificial knee joint that replaces the lower leg for a transfemoral amputee.

Purchasing power parity (P.P.P.)

The purchasing power of a currency is the quantity of the currency needed to purchase a common basket of consumer goods and services. PPP equalizes the purchasing power of two given currencies by accounting for differences in the cost of living and inflation in the two countries.

Quality of impact evidence

Internal validity is the extent to which we are able to say that no other variables except the one under study caused the result. In other words, high internal validity denotes a degree of confidence that we can attribute causation (in some ways, another way of saying “impact”) to the intervention.

Randomized controlled trial (R.C.T.)

A randomized control trial is an evaluation design by which individuals (or groups) are randomly allocated into treatment and control groups, where the treatment group receives the program. The outcomes of the two groups are then compared in order to estimate effect size. See also Effect Size.

Referral facilities

Health care facilities that accept referrals for acute illness.

Referral facilities

Facilities to which patients are referred, usually from primary and secondary care facilities. Referral facilities provide care for high-acuity patients.

Relevance

Evidence from elsewhere is relevant to a nonprofit's program if two conditions are met. First, the program must fit the conditions for external validity of the study. Second, the study must be of high quality.

Research and development

Activities conducted to improve existing products and processes, or to develop new products and processes.

Resource-limited medical settings

Commonly used term in the medical literature to describe places where patients and providers have small budgets for health care, effectively restricting access to expensive therapy. For example, see Andrea L. C, Yuchiao C, Andrea V. M, Adam B, Ingrid V. B, Rochelle P. W, et al. Effectiveness of Pediatric Antiretroviral Therapy in Resource-Limited Settings: A Systematic Review and Meta-analysis. *Clinical Infectious Diseases*. (2009); (12): 1915. Available from: JSTOR Journals.

Restricted donations

A nonprofit's use of restricted donations is limited to particular purposes by the donor. See also Unrestricted Donations.

Sample

The sample is the portion drawn from a population for testing or analysis that is intended to enable statistical estimates of the behavior or attributes of the whole population.

Sample size

The sample size is the number of units that comprise the sample. The sample size determines the minimum effect size that the research design will detect. Power calculations are used to determine the appropriate sample size for a research design.

Savings and Credit Constraints

Savings and credit constraints exist when people are limited by a lack of resources saved and a lack of borrowable resources, and are therefore unable to make productive investments that could raise their standard of living. See also Poverty Trap.

Scaling stage

A nonprofit at the scaling stage is in the process of expanding its program.

Social inefficiency

The social inefficiency is the result of the underlying market and government failures. It is the primary reason that the nonprofit's intervention is socially beneficial. It effectively answers the so-what question: if a skeptic is willing to grant that the underlying market or government failure exists, then, "So what?"

Statistical significance

A statistically significant result (often a difference of means of the main outcome of interest) is a result that is unlikely to arise as a result of chance. This doesn't mean the finding cannot be due to chance – just that it is very unlikely.

Systematic review

A type of literature review that collects and analyzes multiple research studies in order to answer a research question. After a research question is defined and appropriate research studies identified, data from the studies are extracted, assessed for their quality, analyzed, sometimes statistically combined in meta-analyses, and reported in such a way as to address the research question.

Targeting

The process of identifying beneficiaries to be recruited for participation in the program. Targeting is said to be effective when beneficiaries match the nonprofit's intended criteria. The rate of leakage refers to the number of individuals who benefit from the program but do not meet those criteria.

Targeting data

Targeting data are one form of monitoring data that tracks the identification of beneficiaries to receive the program.

Theory of change

A theory of change connects the problem to the intervention the nonprofit runs to expected process and outcome metrics. The objective of a theory of change is to provide a testable hypothesis for why the intervention is solving some problem that will lead to positive changes for the targeted beneficiaries. In an impact audit, ImpactMatters requires that the problem be framed in terms of a market failure or government failure.

Transfemoral amputees

A patient that has had the leg amputated above the knee.

Treatment effect

The change in an outcome variable attributed to a specific dose of treatment. In a difference-in-differences framework, this is the amount by which the treatment group's change in the outcome variable exceeds the same change in the control group, on average.

Treatment group

In an experiment, the treatment group is comprised of experimental subjects that receive the treatment being evaluated. Also known as an intervention group. See also Control Group.

Unmet need

In the public health literature, the unmet need of a population refers to the difference between health services deemed necessary and health services actually received.

Unrestricted donations

A nonprofit's use of unrestricted donations is not limited to any particular purposes by the donor and may be used as the nonprofit sees fit. See also Restricted Donations.

Validation stage

A nonprofit at the validation stage is testing its program's impact.

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