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

ImpactMatters

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.

INTERVENTION	ENGAGEMENT	IMPACT
D-Rev designs, develops, licenses and distributes affordable medical devices that meet the needs of low-resource health facilities, including a phototherapy device for neonatal jaundice and a prosthetic knee.	Number of devices effectively in use	Deaths and disabilities averted (reported in DALYs)

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D-Rev only collects data from hospitals that are easy to reach and relies on assumptions about device use that may be out of date.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

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.

ImpactMatters, a 501(c)3, conducts "impact audits" of nonprofits to rigorously estimate their philanthropic impact, compelling them and their funders to make evidence-based decisions.

Woeful accountability plagues the philanthropic marketplace. Our impact audits provide a creative, promising solution.

Funders pour money into nonprofits in pursuit of philanthropic wins. They fund health programs, education initiatives and an uncountable number of other interventions. And what do funders know about the impact of their grants? Nearly nothing. The system squanders precious philanthropic dollars because accountability is weak if not non-existent.

What explains the systemic failure? For starters, philanthropic assessment is hard, calling for sophisticated social-science modeling. Only a handful of funders – be they foundations, charities or individual donors – have the capacity to correctly assess philanthropic impact. Making matters worse, only A+ nonprofits have incentive to help funders out by undergoing rigorous assessment. In the current system, typical nonprofits suffer no penalty by eliding assessment. The upshot? The lack of incentives to demonstrate outcomes – the lack of a credible rating system for nonprofits – leads to billions in wasted dollars.

ImpactMatters conducts "impact audits." The audits certify whether the claims made by nonprofits about their impact are supported by professional assessment of data. Our vision is ambitious. We seek to reshape philanthropy by creating an industry standard for assessment of impact.

Learn more at www.impactm.org.

ImpactMatters