"It's not just hacking for the sake of it": a qualitative study of health innovators' views on patient-driven open innovations, quality, and safety

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Authors and affiliations:

Lysanne Rivard, PhD
Senior Research Advisor, Center for Public Health Research, Université de Montréal

Pascale Lehoux, PhD
Professor, Center for Public Health Research, Université de Montréal

Hassane Alami, PhD
Post-doctoral fellow, Center for Public Health Research, Université de Montréal

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Correspondence:

Pascale Lehoux, pascale.lehoux@umontreal.ca

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Abstract

Objectives: Open Do-It-Yourself (DIY) health innovations raise new dilemmas for patient- and service-oriented scholars and healthcare providers. Our study aimed to generate practical insights into quality and safety issues to patient care raised by two volunteer-run open DIY solutions: Nightscout Project (patient-driven open-source software for Type 1 diabetes management) and e-NABLE (volunteers who design and 3D print upper-limb assistive devices). To this end, we examined the views of health innovators who are knowledgeable about medical devices standards and regulations.

Methods: We applied a multimedia-based data-elicitation technique to conduct in-depth interviews with a diversified sample of 31 health innovators practising in two Canadian provinces (Quebec and Ontario). An exploratory thematic analysis approach was used to identify respondents' reasoning processes and compare their overall judgements of Nightscout and e-NABLE.

Results: Respondents pondered the following quality and safety issues: importance of the need addressed; accessibility; volunteers' ability to develop and maintain a safe solution of good quality; risks involved for users; consequences of not using the solution; and liability. Overall, innovators see Nightscout as a high-risk DIY solution that requires expert involvement and e-NABLE as a low-risk one that fills a hard to meet gap.

Conclusions: Health innovators generally support patient-driven initiatives but also call for the involvement of professionals who possess complementary skills and knowledge. Our findings provide a list of issues healthcare providers may discuss with patients during clinical consultations to document potential risks and benefits of open DIY solutions. To inform new policy approaches, we propose the development of publicly funded umbrella organisations to act as intermediaries between open DIY solutions and regulatory bodies to help them meet quality and safety standards.

INTRODUCTION

Because the health innovation industry usually follows technology-driven dynamics where investors seek high returns on their investments,(1) companies tend to focus on commercially successful medical devices while neglecting patients' self-identified needs.(2-4) As a result, patients who regularly experience discomfort or frustration when using medical technologies in their daily lives often abandon their use or search for alternatives.(5) To this end, "citizen 'Health Hackers'" worldwide have been inspired by open-source, open-design, and do-it-yourself (DIY) approaches to innovation and are bypassing medical companies to make the technologies that better meet their needs.(6)

Developed by software coding communities(7) and maker cultures,(8) these approaches are generally conducted in an open collaborative manner where individuals share their design tools and processes(9) so that anybody may build their own products.(10) Proponents list many advantages, including reduced costs,(9, 10) fast innovation cycles,(11) adaptable designs(10) as well as improved accessibility, sustainability,(9) inter-operability, safety, and security.(10) Of note are the #WeAreNotWaiting community, where patients and caregivers develop open DIY health technologies for diabetes management,(6) and the field of open DIY assistive technologies,(12) which is driven by more accessible 3D printing and by many users' lack of access to(13) or satisfaction with their devices.(14)

Though open DIY initiatives remain marginal in the health field,(11) they are drawing increasing academic attention for their capacity to innovate and their potential to improve healthcare.(6, 13, 15-19) For some scholars, this bottom up movement(16) indicates how the provision of healthcare is now shared between institutions, providers, and citizens who are actively involved in finding solutions to their problems.(20) This is aligned with the views of quality improvement scholars who advocate for the coproduction of quality with patients(21) and who invite practitioners to rethink healthcare as a service built with patients, which values their capacity to manage their health.(22)

However, the priority of open DIY innovations being to better meet patients' needs in an accessible manner, many initiatives do not follow established innovation development industry standards or medical devices regulations because doing so is time-consuming, complicated, and expensive.(9, 23) Numerous quality and safety issues are thus raised, mostly resulting from the lack of data security standards and untraceable development processes and materials.(11) This is especially the case when innovation development and maintenance largely depend on volunteers.(24) In addition, because open DIY solutions may be used in conjunction with medical devices that obtained market clearance for a specific indication, healthcare providers (HCPs) must sort out confusing liability issues when attending to patients who use or consider using a mixed solution (e.g., a DIY innovation that relies on an off-label use of an existing medical device).(15, 25, 26)

Because the current literature focuses on the views of patients(16, 27-30) and relies on single case studies(12, 19, 31, 32) or opinion pieces,(6, 15, 17, 18, 25, 26) the objective

of this qualitative study was to generate practical insights into the quality and safety issues raised by two volunteer-run open DIY solutions exemplifying current trends in user-developed and open-source health innovation. Towards this end, we gathered the views of experts in related fields with a focus on how two innovations– Nightscout Project(6, 25-30, 33) and e- NABLE(10, 13, 14, 34) – impact quality and safety concerns.

METHODS

Participant recruitment

We recruited a purposeful and diversified sample of 31 health innovators trained in engineering, industrial design, medicine, and/or business, who are knowledgeable about and required to follow industry standards and regulations, and practising in the two largest Canadian provinces that are the most active in the medical device industry (Quebec and Ontario). Through an extensive online search, we specifically looked for professionals active in the design, development, and/or commercialisation of innovative health technologies and recognized as leaders in their field (e.g. award-winning innovations). Potential participants received a personalised email describing the study and why they were invited to participate. We sought parity between the genders and the provinces, as well as a balanced representation of the professional backgrounds. The university's health research ethics review board approved this study and respondents provided written informed consent prior to their interview.

Study design

The selection of Nightscout and e-NABLE took place within the context of a broader study aiming to explore health innovators' perspectives on what is and is not responsible innovation in health.(35) Through an online horizon scanning, we first identified 105 innovations that illustrated various responsibility considerations. Then, with the help of a multidisciplinary committee, nine innovations were selected, including Nightscout and e-NABLE.

The qualitative study design entailed a multimedia-based data-elicitation technique, which relied on a website to briefly introduce each innovation and prompt participants' reflections about the issues they raise prior to a semi-structured interview.(36, 37) Created by our research team, participants found on this website an image of each innovation, a summary of its characteristics, hyperlinks, a list of references, and a printable document where they could write down personal notes and reflections. Boxes 1 and 2 reproduce the information provided to respondents. The information was drawn from the innovations' website, scientific publications, and reports by non-governmental agencies. The goal was not to provide respondents with a summary of the evidence but rather to stimulate their own reflections and further discuss during the interview the tensions and practical implications of adhering (or not) to established regulations, industry standards, and corporate practices.(35) Respondents were notified that the research team does not endorse these innovations.

Box 1. Information about Nightscout shared with participants through the study website

NIGHTSCOUT A cloud-based software that helps children with diabetes

The challenge: Managing Type 1 diabetes requires a precise combination of insulin injections and the consumption of carbohydrates. A proper monitoring of glucose levels diminishes the risks of complications related to the disease. Diabetes is ranked 12th in the list of causes of the global burden of disease.

The innovation: Nightscout is a cloud-based software that enables the continuous monitoring of glucose (CGM) levels in real-time for children with Type 1 diabetes. The Nightscout technology was developed by CGM users with the collaboration of an online community of patients, their parents, and healthcare providers, all of whom share their knowledge and time on a volunteer basis.

How it works:

- The technology helps patients with diabetes and their caregivers to better manage the disease and could reduce the workload of healthcare providers.
- Nightscout is an open-source project and improvements are made over time. Instructions for its use are downloadable and the installation can take anywhere from 30 minutes to several hours.
- Code functionality cannot be guaranteed since the project was created and developed by volunteers. Each element of the system can fail at any time and render it unusable.

The cost:

- The innovation is free and the Nightscout Facebook group (CGM in the Cloud) offers free technical support for all users. As of June 14th 2017, the group reached over 23,000 members.
- Though the innovation is free, it functions with a CGM system and requires the use of electronic devices like smartphones or smartwatches. The global cost of using Nightscout depends on the devices used and on Internet access (Internet plan or Wi-Fi).
- There is no cost-benefit analysis available at the moment.

The approval status: The Nightscout system is not yet approved by the Food and Drug Administration of the United States of America. Other mobile solutions that display glucose levels on electronic devices using CGM systems do exist and are already approved.

Box 2. Information about e-NABLE shared with participants through the study website

E-NABLE A network that makes free 3D-printed mechanical prostheses

The challenge: Traditional prostheses cost an average of US$8,000. The amputation of one or more upper limbs can result from, amongst other causes, congenital abnormalities, road injuries, self-injury, or interpersonal violence. These are ranked in the top 25 causes on the list of causes of the global burden of disease.

The innovation: The e-NABLE community stands apart from traditional prostheses manufacturers by connecting volunteers who design 3D-printed upper limbs with people who need them. Models are created using a collaborative approach where printing plans are made available at no cost. Prostheses are printed free of charge from anywhere in the world and delivered directly to the user.

How it works:

- e-NABLE designs created by volunteers are open-source and shared on Thingiverse, a site dedicated to the sharing of digital design files created by its users. It also connects volunteers with people wishing to try 3D-printed prostheses.
- The prostheses are mechanical, do not need electricity, are customisable, and easy to assemble.
- The e-NABLE prostheses work particularly well for people with a full or partial palm and 30-degree wrist motion. They cannot be used in manual labour-intensive environments.
- Children can easily use the prostheses because the latter can perform simple tasks, such as holding a ball, pressing buttons, and turning pages.
- Between July 2013 and June 2015, e-NABLE volunteers made approximately 1,500 prostheses for children and adults in over 40 countries.

The cost:

- The prostheses created and printed by e-NABLE volunteers are free.

The approval status: e-NABLE prostheses have been evaluated by clinical studies but have not been approved by organisations such as the Food and Drug Administration of the United States of America.

Data collection and analysis

Between March and July 2018, the first author, who is fluent in French and in English, conducted the interviews over the phone or in-person in French (n=14) or in English (n=17). They lasted between 30 and 60 minutes, were audio-recorded, and transcribed verbatim. The interview questions (see Supplementary Material) supported a dynamic discussion between the interviewee and interviewer where the latter asks the same questions to each respondent and uses probes to increase depth and clarify their views.

Following an inductive exploratory thematic analysis approach, the first author used Dedoose 8.0.42 to develop preliminary codes that were then refined with the second and third authors. She then coded the whole dataset, applying the agreed upon coding framework. Code-ordered matrixes were created to identify variations and similitudes across respondents' views regarding the quality and safety concerns raised by the two innovations.(38) Using these matrixes, our analyses then sought to clarify why respondents came to different conclusions for each innovation regarding their overall quality and safety and discerned from the overall results their shared concerns. We did not aim for empirical saturation but rather to identify the spectrum of quality and safety issues raised by participants from the diverse professional backgrounds that underlie health innovation practices.

We use the letter P to designate "participant" and numbers to designate the respondents following the order in which they were interviewed. The manuscript was prepared according to the Standards for Reporting Qualitative Research guidelines.(39)

RESULTS

Table 1 describes the study participants. Six themes gradually emerged as characterising respondents' reasoning processes (i.e., lines of argumentation enabling them to draw an overall conclusion), which considered:

- Importance of the need addressed
- Accessibility
- Volunteers' ability to develop and maintain a safe solution of good quality
- Risks involved for users
- Consequences of not using the solution
- Liability

With illustrative quotes (translated from French to English by the first author when applicable), our findings successively describe respondents' views about Nightscout and e-NABLE and then clarify why innovators see the former as a high-risk DIY solution that requires expert involvement and the latter as a low-risk one that fills a hard to meet gap.

Table 1. Description of study participants

	Participants (n=31)
Province	
Quebec	16 (52)
Ontario	15 (48)
Gender	
Female	17 (55)
Male	14 (45)
Training	
Engineering	7 (23)
Medicine and other clinical sciences	9 (29)
Entrepreneurship	9 (29)
Industrial Design	6 (19)

Position	
Faculty member/Researcher	9 (29)
Founder/Co-founder, Chief Executive Officer, and/or President	7 (23)
Senior management	5 (16)
Other (e.g. senior advisor, specialist, postdoc, etc.)	10 (32)
Area of specialisation	
Medical device	17 (54)
Digital solutions	7 (23)
Robotics	2 (7)
Other (e.g., health products, lab work, etc.)	5 (16)

n, sample size.

Nightscout: a high-risk innovation that requires expert involvement

Importance of the need addressed

By providing real-time access to a child's Type 1 diabetes data, respondents stressed that Nightscout addresses an important need and can be "very beneficial to patients and parents" [P31]. They argued that this "critical information" [P25] helps parents to "better control" their child's diabetes [P24], thus reducing the burden of a chronic illness [P30] that "is potentially life threatening" and helping Type 1 diabetes patients and their families "have a normal life" [P28]. For example, a biochemist explained how Nightscout changed the life of a friend whose daughter's glucose levels could not be monitored at school:

> She had to quit her job and go to the school every day, like eight times, to check her daughter's blood sugar. So, she took the code that was published online and she literally hacked her cellphone and her daughter's pump and then got her life back, took a job and so […] it's not just hacking for the sake of it. [P17]

Accessibility

Respondents considered that such an open-source model increased accessibility by offering the software free of cost [P8, P12, P21, P28, P31].

Volunteers' ability to develop and maintain a safe solution of good quality

A more contentious issue was whether volunteers could develop and maintain an open-source digital health innovation that is of good quality and safe to use. Though some respondents underscored the importance of patient-driven innovations, many argued that volunteers generally lack the expertise required to develop and maintain reliable and safe digital health solutions. Five key issues that volunteers may not be properly equipped to handle included: industry standards for code development, quality management standards for medical devices, privacy regulation and law, regulatory approval procedures for clinical validity, and system maintenance. For example, an engineer explained:

> I have learned enough with our ISO-13485 standards [International Organization for Standardization regulatory standards for medical devices] and the processes to do

> products that you have absolutely no quality control when it's being used by multiple people providing software into this product. […] I'm absolutely quite convinced if it needed FDA [Food and Drug Administration of the United States of America] approval, it would never make it. [P27]

Risks involved for users

Respondents raised risks of a system failure and breaches to data privacy and security. A digital health entrepreneur explained how even though she thought Nightscout was "innovative" and appreciated how parents responded to their "real need," she felt that the innovation's development was "unsafe" and was "concerned" about the "end product":

> I would prefer that this was not open-source code that had been created by volunteers […] I would feel uncomfortable not having developers watching and looking after that code, because if something fails, you could put a child's life at risk. […] there is disclosure, that's good, but when these parents created it and put it together, did they think about the privacy regulations and the privacy law, […] where's that information being stored, how is it being transmitted, and how easily is it hackable? [P25]

Interestingly, only one respondent acknowledged the Facebook group Continuing Glucose Monitoring in the Cloud as offering technical support to Nightscout users [P16].

Consequences of not using the solution

Regarding the potential consequences of not using Nightscout, a clinician with digital health expertise distinguished a "good open-source community" that can rapidly "respond to changes in the hardware" from one that does not and judged that Nightscout's overall benefits outweighed this risk [P24]. An entrepreneur concluded that there was little "risk of anything bad happening in comparison to the actual good that can happen" because "the child [could] still use the base monitoring system" to read glucose levels in case of failure of the Nightscout cloud-based system [P12].

Liability

Lastly, respondents questioned who is liable for the innovation. A digital health engineer summarises the issue:

> let's say that your system has crashed, and then overnight your kid had an event and you miss that because you are over relying on the technology that you're using. So, who's responsible for that? […] there's nobody actually 24/7 on their technical side monitoring their system to make sure that it's always right. [P31]

A physician questioned whether patients properly understood the liability implications of using an open DIY solution in comparison to a clinically tested and regulated medical device: "I think people take it at face value and assume that it's the same as something that has been approved and that's not the case" [P13]. Indeed, failing to have expert involvement was a recurring concern. Suggestions included providing government support to help "bring the technology up to the necessary standards" [P31], developing a

company that can ensure "it's done well and to certain guidelines" [P8], or for user and expert communities to work together in order to tap into the benefits of open DIY solutions while mitigating the risks [P22].

After deliberating the issues presented above, only four respondents remained positive about Nightscout's value. For the others, it posed a high level of risk to users and thus quality and safety concerns outweighed its likely benefits.

e-NABLE: a low-risk innovation that is 'better than nothing'

Importance of the need addressed

For several respondents, e-NABLE addressed an important need because of its capacity to provide upper-limb mechanical assistive devices free of cost to those who otherwise would not have access, thus responding to "an important public health need" [P4].

Accessibility

Two characteristics made e-NABLE's prostheses accessible: 3D printers that are now easy to use and affordable and computer assisted design models and blueprints that are open-source or open-access. For instance, a clinician evoked a YouTube video where a 10-year-old boy "created his own prosthetic with 3D printing" [P29]. However, two respondents questioned e-NABLE's accessibility. For a physician, the prosthesis is free for the user, but volunteers must cover production costs and the network can probably reach only "a very limited fraction of the population" in need [P13]. As a result, he argued that e-NABLE is "not a public health solution" to the public health need [P13]. For a clinical researcher, the use of 3D printing may not guarantee a reduction of cost in the long term because the cost of base materials will fluctuate with the demand [P19].

Volunteers' ability to develop and maintain a safe solution of good quality

As for volunteers' capacities to develop and maintain good quality and safe health innovations, some respondents argued that a large network of volunteers was an asset, while others questioned their capacity to make quality prostheses. For some entrepreneurs, working with "so many different volunteers" could create a greater variety of customised models [P25] and offer a diversity of skills to help solve "different challenges" [P12] as "people who voluntarily spend their free time developing these sorts of things are passionate people who generally know what they are doing" [P11]. An engineer with expertise in prostheses explained how even though professionals who build the devices receive specialised training, they are not part of a professional order and therefore prostheses are not standardised, regulated, or certifiable, but rather each device is "a work of art" [P4]. Thus, volunteers could also build these devices. Yet, for an industrial designer, the quality of prostheses was compromised by the type of 3D printers used by volunteers: "the problem is that volunteers often have a printer worth 2 000$ whereas to do a good job,

you need a 100 000$ printer" [P5]. Furthermore, an entrepreneur was concerned with the varying levels of volunteers' experiences in making prostheses [P21].

Risks involved for users

In terms of the risks involved when using a volunteer-made prosthesis, respondents identified the risk of injury resulting from an improper fit or use. An industrial designer explained how volunteers' lack of expertise in biomechanical and ergonomic design could put users at risk:

> here's the scenario: I'm not qualified to do this, but I'm good at doing CAD [computed assisted design] models and I design the prosthetic, I give over the printed files, it gets printed, [the user] puts [it] on and develops injuries over time because it's not designed with regards to biomechanical considerations or fit or […] human factors and ergonomics considerations to make it comfortable [and] safe in terms of physiological function. [P22]

Consequences of not using the solution

For others, an e-NABLE prosthesis would probably not be "nearly as good as an expensive one" [P27] or "highly efficient" [P4], but it still represented a low level of risk because "it's not intrusive" [P9] and if it does not work, one simply removes it [P3]. Indeed, several respondents weighed the overall risk against the consequences of not using the DIY solution and concluded that the social and psychological advantages were greater than the risk of minor injury. A digital health engineer summarises this perspective:

> The beauty of this group is that they can build very, very cheap prostheses for kids. Are there risks associated with that? Of course, there are. The kids might hurt themselves trying to hold heavier objects, it may affect their development because the prostheses are not necessarily built considering the physical development of the kid […] But again, we're talking about a population that would not have access to a prosthesis otherwise. So, I feel that the community itself will evolve over time to address some of these issues, I feel that the risks associated with the mechanical prosthesis are much lower than Nightscout. [P31]

Liability

Finally, liability was mostly discussed in terms of offering follow-up care to ensure proper fit and function. For an industrial designer: the "piece that would be wonderful to have is the physiotherapist or some involvement where there can be assessment and follow-up, and that would mitigate risks" [P22].

Overall, in contrast to Nightscout, only one of the respondents who deliberated e-NABLE's quality and safety concerns concluded that it was not desirable. For the others, the benefits resulting from the use of a prosthesis for those who otherwise would not have access outweighed the risk of injury.

DISCUSSION

As the open DIY health innovation movement draws attention for its potential to both help and harm users, it intersects with the patient- and service-oriented quality and safety scholarship and raises new dilemmas for HCPs.(18, 20) Our qualitative study thus aimed to generate practical insights into the phenomenon by gathering the perspectives of practitioners who regularly deal with medical innovation industry standards and regulations. Our results indicate that respondents' overall judgment of two volunteer-run open DIY solutions was conditioned by: importance of the need addressed, accessibility of the solution, volunteers' ability to design and maintain a safe solution of good quality, risks for users, consequences of not using the solution, and liability issues. These findings add to current knowledge in two ways.

First, our study underscores that health innovators are generally supportive of patient-driven and open solutions because they address user needs and improve accessibility. This is aligned with studies showing the life changing impact of Nightscout for caregivers(27-30) and e-NABLE volunteers' commitment to making accessible assistive devices.(14) However, our findings make more explicit innovators' reasoning processes, that is, how they weigh the risks and benefits of each solution in view of the severity of potential harm to users. For instance, while the e-NABLE volunteers interviewed by Parry-Hill et al. were concerned with the risk of injuring users(14), our respondents generally considered e-NABLE's mechanical shortcomings less harmful than the potentially life-threatening consequences of a Nightscout software malfunction.

Second, our findings indicate that health innovators call for a safer deployment of volunteer-run open DIY solutions, one that should rely on a clear liability framework and experts' support. Liability is a key issue for HCPs caring for patients who may not disclose their use of DIY solutions(40) and for users who may not know what liability entails.(15) Both Nightscout and e-NABLE raise important liability concerns. Because Nightscout is free, it is not regulated by the Food and Drug Administration of the United States of America.(25) As for e-NABLE, the clinicians interviewed by Parry-Hill et al. sought to reduce potential liability issues by avoiding interactions with recipients and only providing feedback to volunteers making the devices.(14) With a similar aim in mind, our respondents emphasised the importance for DIY communities to obtain experts' support and formulated practical suggestions to do so. For instance, although Nightscout's original code was developed by a caregiver software programmer,(25) the majority of its users rely on the Facebook group for technical support.(30) Such patient-driven initiatives could be better supported by working with a variety of professionals who possess complementary skills and knowledge in order to effectively and safely meet users' needs, a recommendation supported in the literature.(12, 14, 25, 31, 32, 34)

Implications for practice and policy

Our findings can inform both practice and policy approaches to open DIY health innovations. For HCPs, our findings offer an initial list of issues they can discuss with patients during clinical consultations, such as: whether the need is significant; the solution

is accessible, well designed, and safely maintained; the risks for users; the consequences of not using the solution; and the liability issues. By integrating a discussion of these issues in their practice, HCPs could clinically document the potential risks and benefits of open DIY solutions on a case-by-case basis for each patient.(18)

At the policy level, our respondents' concerns with providing access to safe and good quality innovations developed by users lend support to scholars who underscore the lack of institutional environments that can support users to develop safe solutions (34) as well as those who argue that a "multi-level body of governance" could encourage the spread and adoption of such solutions.(41) To help mitigate the risks of open DIY solutions while maximizing their benefits in future patient-driven and service-oriented care, we propose the development of publicly funded umbrella organisations to act as governmental intermediaries between individual open DIY solutions and regulatory bodies. Following International Organization for Standardization norms for good governance, umbrella organisations could provide the expertise and support needed for these initiatives to meet formal quality and safety standards. They could operate under a limited liability basis to offer a shared secured digital backend that respects the requirements of the American Health Insurance Portability and Accountability Act and the European General Data Protection Regulation.(42) Such a policy approach would explicitly include patient groups and volunteers who possess key skills and relevant experiential knowledge.

Strengths and limitations

Though our qualitative data collection and analysis strategies followed rigorous methodological standards and brought forward six key themes that can inform both practice and policy, four limitations should be kept in mind. Nightscout and e-NABLE exemplify key trends in user-developed and open-source health innovation, but evidence about their benefits and risks is still evolving. The information we shared with respondents was very succinct and some statements may have been misleading. Participants' prior knowledge of either innovations may have led to potential biases for or against the latter. Because we recruited participants interested in responsibility issues, our results may overestimate health innovators' awareness of and sensitivity to quality and safety issues.

Because regulatory frameworks vary from one country to another as well as the support patient groups may obtain from public authorities, the transferability of our findings is limited to settings similar to those of our respondents. While some were familiar with the challenges raised by digital health solutions, others were with the challenges of medical devices, and all practiced in a North American context. Only a few respondents had experience with health innovations in low- and middle-income countries.

Further research

Further research could build on our qualitative and exploratory study by conducting enquiries with a broader and more diversified set of open DIY health innovations. In addition, researchers could further explore how the list of issues raised by our respondents may be expanded and adapted to meet the emerging needs of HCPs and their patients in

their use of open DIY health innovations. Finally, scholars may be interested in further developing our proposal of an umbrella organisation to help open DIY health initiatives meet quality and safety standards.

Conclusion

Because open DIY health innovations are likely here to stay, quality and safety scholars and practitioners will need to respond to their emergence, use, and dissemination and support productive discussions with patients and caregivers about their potential benefits and shortcomings. While we propose the development of public umbrella organisations that mediate between open DIY solutions and regulatory bodies, it will be important to pursue policy-oriented research on ways to support innovative patient-driven and service-oriented care.

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ORCID iD: Lysanne Rivard http:// orcid. org/ 0000- 0003- 4650- 2543

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