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Advantages and limitations of online communities of patients for research on health products[☆]

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Summary   The way patients and their caregivers share information on various online platforms about health topics and their own experiential knowledge presents new potential environments for research, particularly as concerns health products. The information provided individually and voluntarily by patients who are members of these online communities is a new resource for identifying and understanding precisely how health products are used, assessing their effectiveness, quantifying potential adverse effects in real-life situations, detecting subtle signs that are significant for experts in pharmacovigilance and addiction studies, and developing new assessment tools to help form new working hypotheses. How patients freely express their experiences and feelings and the reality of what they share also opens the way for societal research into health products, a field that is still under-explored. Well-established regulations govern research into health products, which uses resources and methodologies that have changed little over the years. However, the development of online communities of patients presents new possibilities in this field. The challenge we face today is defining their place among traditional research techniques. This place cannot be accepted by all stakeholders unless we first establish a firm understanding of the advantages, limitations, and constraints of these communities. The round table on this topic endeavoured to: explore these issues and develop a better understanding of the phenomenon and the different varieties of online communities and networks for patients; identify possible advantages, special features, and methodological, regulatory, and ethical limitations that researchers currently face; and finally, to put forward the first recommendations in this growing field of research.

Abbreviations

ALP   automatic language processing
ANSM   *Agence nationale de sécurité du médicament et des produits de santé* (French Agency for the Safety of Medicinal and Health Products)
IRB   institutional review board
FMTI   French multi-terminology indexer
MedDRA medical dictionary for regulatory activities
PRO/PRI patient-reported outcomes/patient-reported information
SMTS   *serveur multi-terminologies en santé* (multi technology health server)
SNOMED systematic nomenclature medical clinical terms
UMLF   unified medical lexicon for French
UMLS   unified medical language system

Introduction

Internet users have appropriated new features of the web, creating what is referred to as Web 2.0, which provides more opportunities for interactions and information sharing. In recent years, this development has led to the emergence of different social systems, including social networks, blogs, wiki pages, and interactive community platforms. Health, a daily preoccupation for many, rapidly became one of the preferred topics for internet users surfing these sites, showing how willing individuals were to become actors in their own medical care. The internet is an easy-to-use tool offering numerous possibilities, from conducting simple searches for information to actively participating in building up our knowledge of a condition by sharing personal experiences, thereby encouraging patients and their caregivers to reach out and become sources of information themselves. The round table on this developing current topic set the following goals: clarifying the different types of online patient systems or communities identifiable on the internet; understanding the special features of each type; and considering the possibilities, advantages, and limitations of how these media and the resulting data could be useful and valuable for research and for creating research partnerships. This discussion was conducted with an understanding that it overlapped in some aspects with the topics covered by another round table in 2015 including data accessibility and ownership and more generally issues relating to data warehouses, patient databases, big data, and open data [1]. Furthermore, the continual creativity of users, their role in assessing health solutions, digital technological advancements, and innovations in telemedicine, e-health, artificial intelligence, and connected objects will continue to add to and improve these discussions.

Members of the round table also attempted to draw on their varied professional experience (from working as consultants, clinicians, clinical research managers, pharmacoepidemiologists, health product manufacturers and from working with patient associations and marketing platforms, etc.) as well as analysis of available literature to reveal certain key factors that online patient communities bring to research. The goal of these efforts is to propose recommendations that can act as a reference for all operators in this field and in the research community.

Current landscape of online patient communities

Today, these communities seem vast and limitless because of the exponential growth of tools and data as well as users' boundless interest in health and the explosion in the number of tools for patients and their caregivers to express themselves. These factors all contribute to a sort of data deluge that is a largely untapped resource. Here are some examples:

- ninety percent of the data generated by people was generated in the last two years (source: IBM);
- in 2015, 86% of French people reported that if they were to develop a disease, they would like to be able to connect with other patients with the same disease [2];
- in 2016, 68% of French people reported consulting the internet to find medical information. The main sites consulted were informal and collaborative (87%), general information sites for health topics like *Doctissimo* (69%), and purely collaborative sites like blogs, forums, and social networking sites (26%) [3].

There are many names for and variations on this phenomenon: virtual communities, online communities, communities of practice, collaborative websites, blogs, forums, and social networks. These collective initiatives of patients and/or caregivers are more or less structured for ''deliverables'' for research purposes that can be complementary to data from more traditional medical and scientific methods.

The vast majority of these communities do not aim to participate in research. It is nevertheless possible to identify a scale for classifying these communities based on data structure and maturity. According to the round table, distinguishing between commercial (for example, PatientsLikeMe, Carenity), associative (Mon réseau cancer du sein, Diabète LAB, Renaloo), or academic sites (ComPaRe, Seintinelles) is not a relevant methodological approach.

What unites all of these online patient communities of varying sizes is the active individual steps taken by patients and/or their caregivers (to sign up, connect, and participate), hence the frequently-used terms ''patient-reported outcome'' (PRO) and ''patient-reported information'' (PRI) [4].

The voluntary actions and contributions of the patients is what generates the data even if, for Facebook, Twitter, and discussion blogs and forums, patients are not always fully aware of how this data could potentially be used.

Facebook, the largest online community in the world with its 1.5 billion users, makes it possible for patients to organise themselves around medical themes on community platforms for patients to share their experiences (for example, Diabète côté Femme [Women with Diabetes], which has over 31,000 members). Over a two-year period, 2000 health subjects or communities were indexed on Twitter. The completely public nature of tweets does not seem to discourage people from expressing themselves since that number is constantly growing. Forums and blogs, some of them originally individual initiatives, are also new channels for patients to express themselves at varying levels and in more or less structured ways. Personal testimonies dominate and information comes from various sources (scientific, practical, or personal), combining several perspectives.

Whether or not they are commercial, associative, or private, the myriad of platforms and online communities for patients are transforming personal stories into vast databases generated from data provided by patients. Researchers can then use this data to perform a variety of analyses, including demographic, epidemiological, sociological, and clinical analyses (Fig. 1).

Data processing

Once the format has been chosen based on the purpose of the research, the issue of which data collection, extraction, and analysis methods to use arises. Some of these methods require qualitative analyses of the content of textual data, which poses multiple difficulties:

- accessing and recovering data (for example, technical aspects related to the volume of data and whether or not there is access to all of the raw data; legal aspects of data mining, text mining, copyright, and using bots to collect data);
- rebuilding blocks of information and discussion threads (since information in a message may refer to the title of the discussion thread or even the title of the forum, for example, it is sometimes necessary to analyse these differing levels of information together) or choosing a method for processing unstructured data in groups of words or point or word clouds;
- choosing the type of analysis to use: searching for meaning by analysing thousands of co-occurrences of terms or using automatic language processing (ALP) with morphosyntactic, lexical, and semantic analysis (identifying nominal, verbal, prepositional, and adjectival phrases and their relations; identifying negations, temporal indicators, and level of certitude through use of the conditional, conjecture, suggestion of suspicion, etc.), though ALP is very language-dependant and requires a large, manually-annotated corpus;
- creating a patient thesaurus or glossary that connects patient terminology with a reference (for example, connecting ''I stayed up all night'' to the medical term ''insomnia'' so it can be aggregated and processed) — this is important because patients do not consult the medical dictionary for regulatory activities (MedDRA) dictionary or other standardised medical terminology sources and instead use less complex and more common expressions. Sometimes, creating a glossary is not enough because the structure of the entire sentence is what conveys meaning (for example, I didn't catch a wink all night'').

Automated methods, still in their preliminary stages in France, are currently being tested, as in the ''drugs-safe'' project, a pharmacoepidemiological platform for systematised assessments of drug use in the population, which is supported by the French Agency for the Safety of Medicinal and Health Products (*Agence nationale de sécurité du médicament et des produits de santé* or ANSM) [5]. One aspect of this research is the attempt to identify potential misuse of drugs through discussion forums which requires understanding how normal use appears in these forums and
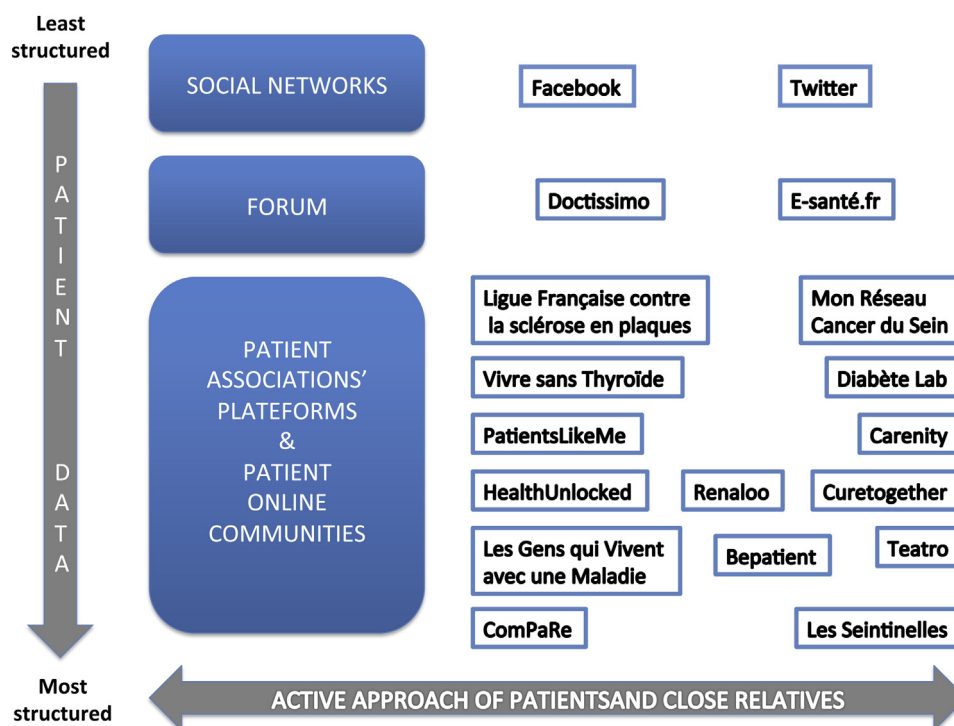
Figure 1.   Current preview of virtual patient communities.

then providing tools to statistically visualise atypical use, given the indications, contraindications, and known adverse effects of the molecules in question. The DIPEx project from Oxford is also worth noting. It is both an associative and academic platform that has generated 50 publications thanks to the support and methodological assistance of the university [6].

Types of research possible

In the field of research into health products and their environment, data collected and reprocessed this way may potentially be valuable for all stages of research, from generating a hypothesis and proof of concept to addressing the questions patients face in dealing with their conditions and the treatments they are prescribed to analysing real usage. Potential applications include (Fig. 2):
- identifying unmet needs;
- designing and carrying out trials;
- selecting and creating assessment tools;
- understanding how patients use health products in real-time;
- creating clinical trials focused on patient data;
- monitoring patients in real-life;
- educating and supporting patients;
- etc.

Analysis of the literature and of personal statements collected has confirmed in all cases that these media have advantages for answering certain questions relating to information about health products, our societal approach, and the organisation of care. However, there are also constraints (for example, legal and methodological constraints) when it comes to using and analysing these media and the results they provide.

Advantages and main contributions of online patient communities and networking for research

Of the potential fields of research, the round table chose to focus specifically on two key activities of research into health products: clinical research and studies carried out in real-life conditions.

Patients on the internet are also an extraordinary source of data, making it possible to take vigilance to another level with: e-pharmacovigilance (or cyber-pharmacovigilance) and e-addiction vigilance by studying blogs, forums, or online communities, but also with social pharmacology, given the sociocultural role of these communities in educating patients about treatments.

To date, there have been approximately 80 publications of work from data compiled through communities like PatientsLikeMe [7], not taking into account other sites like Carenity, which has been operating in France for 5 years and which publishes posters and other forms of communication which are becoming increasingly used in scientific congresses.

Benefits for clinical research and studies in real-life conditions

The following scientific benefits were identified, though this list is not exhaustive.
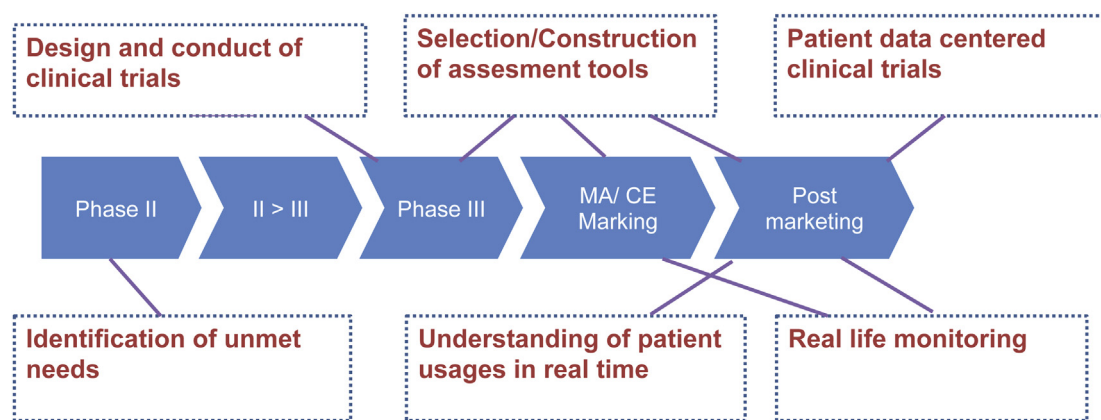
Figure 2. Virtual patient communities: possible fields of research.

Advantages of online patient communities for clinical research:
- exploring patients' expectations and unmet needs.

Patients own descriptions of their expectations and hopes for treatment are extremely rich sources for increasing our understanding of medical needs that are met either poorly or not at all. There are countless examples of this in the literature [8,9]. These methods could assist in identifying unmet treatment needs as they bring researchers closer to communities of patients and caregivers who are likely to provide patient-reported outcomes.
- helping design protocols and tools for research.

The literature abounds with publications on building, improving, or adapting existing tools used commonly in care but rarely in research [10,11] thanks to the use of structured platforms like PatientsLikeMe:
- potentially reinforcing protocols and endpoints in relation to the idea of patient centricity;
- improving and helping a study's feasibility as well as improving recruitment and protocol observance.

Actively listening to patient blogs or soliciting responses through social media and digital communities of patients could promote the feasibility and acceptance of studies. A study carried out in the United States showed that few health product manufacturers sought out feedback or explored aspects of practicality and acceptability of protocols from participants through these methods, though certain platforms offer crowd-sourcing solutions [12,13]:
- carrying out clinical studies for rare, rapidly-changing pathologies [14];
- choosing where to carry out the trial.

Six major areas of studies in real-life conditions that benefit.

Because of the very nature of data spontaneously provided by patients, it is easy to understand that these patient communities are most useful for researchers seeking to understand patients' journeys and real-time habits. The way patients freely express their thoughts also facilities the examination of sociological themes largely unexplored by traditional methodologies used in pharmacoepidemiology.

The six major areas identified are:

- better understanding of the patient journey [15];
- analysis of how the patient feels about their condition (including medicated conditions) and their quality of life [16,17];
- epidemiological data [18];
- assessment of the benefits of various treatment approaches (perceived effectiveness) [19];
- observance of treatment plan, frequency and characterisation of adverse effects, emergence of unusual effects, reasons for switching from one drug to another [20,21];
- effectiveness of the treatment education programme [22].

These two fields of research (clinical research and studies in real-life conditions) have the shared advantage that a specific online community can be created and dedicated to the study.

Patients on the Internet: a source of data

Patients are currently using all possible Internet resources (patient forums, websites, databases, Facebook, Twitter, etc.) to search for information about specific drugs and particularly how effective they are and/or what side effects they have. Consultations of websites and exchanges between Internet users concerning specific drugs could potentially be new sources of information for studying drug usage.

Several groups of researchers have already proven the importance of these resources for assessing real-life drug usage differently. As a complement to data traditionally collected for pharmacovigilance, the analysis of conversations and messages in discussion threads are good sources for assessing use and abuse of drugs and a failure to follow indications, and for searching for possible warning signs.

It is therefore possible in the fields of pharmacovigilance and addiction vigilance to use these resources to detect and confirm warning signs, to characterise patients, specific adverse events or effects, or how drugs are used when prescriptions are not followed. Additionally, it is possible to understand how patients handle adverse events and how their perception of risk changes, and compare these adverse events reported by patients to those from healthcare professionals [23—27]. A recent effort also examined known harmful aspects of forums where inappropriate ''advice''

is given, specifically concerning self-prescription, and the importance of alerting patients to the possible untrustworthiness of these sources in terms of medical advice [28].

Nevertheless, the volume of data generated and the speed at which it is created on social networks provide opportunities to advance pharmacovigilance. A certain number of challenges must however be addressed, especially technical, regulatory, and ethical issues. The critical question that must be answered is: what value do social networks add to the current pharmacovigilance process and what must be put in place to benefit from that value?

Experts in social pharmacology, the study of interactions between society and drugs, are interested in the influence of certain factors on the use of pharmacological substances, independently from purely clinical or rational reasons. Qualitative analyses of patients' language concerning their experience, usage behaviour, well-being, and lifestyle provide interesting possibilities for social pharmacology and could replace costly, restrictive methods that take time to develop such as structured and semi-structured interviews [29].

Other possible themes in social pharmacology that could lead to more research include studying changes in educational schemas and examining the educational role of these platforms [30].

Advantages of online patient communities and networks

Going beyond the typology of online patient communities and networks and whether they are academic, associative, or commercial, the following process was employed to identify their major advantages, grouped based on two attributes: ''patient approach'' and ''methodological advantages'' for research.

Advantages of the ''patient approach''

Since the patient is at the heart of these tools regardless of the kind of tool in question, the patient approach is generally preferred. These tools make it possible to obtain precious information about patients' behaviour, their precise account of their experiences, their similarities, their habits, and their well-being which are difficult to observe using other methods. These resources are available 24/7 for patients and are therefore very flexible and not dependant on operators. The data precisely reflects their daily concerns, which are not necessarily all medical and may also encompass their personal, professional, and home lives. On some websites or in some communities, relative anonymity or the use of screen names encourages patients to spontaneously and sincerely pose questions to their peers in a way they would not necessarily interact with their doctor or caregivers.

The patient approach has the advantage of allowing patients to educate themselves and becoming personally involved by conducting searches (and in associative communities, the patient feels like he or she is actively taking charge of their disease and treatment). This involvement translates into increased mobilisation, and patient motivation is often a key factor in the success of research being conducted. As an actor supported by experience-based

knowledge, the patient can acquire more information through the research opportunity and become a sort of ''expert layman''. Data collected with these methods is complementary to existing, more traditionally collected data. The scope and variety of topics to be studied (for example, pathology, perception of treatment, patient experience and quality of life) present further opportunities for enriching knowledge of health products, particularly after they are marketed.

Methodological advantages

There are essentially two kinds of methodological advantages: those related to the population that can be reached and those related to information processing.

The size of the population that can be reached and the potential volume of data available are both much higher than what has typically been considered possible in the framework of a traditional study (450,000 patients for PatientsLikeMe, 250,000 for Carenity, 3,431,170,192 posts processed by Treato). The consequence of these larger numbers is greater geographic and sociodemographic representativeness, though it still has limitations that must be taken into account when results are announced.

Online patient communities centred around one condition or a restricted number of conditions as well as the structure of certain communities provide valuable access to a population affected by that condition and/or patients who are not part of traditional research and care.

The speed at which information is obtained is an undeniable advantage of these media for information processing and the generation of data. The opportunities for modifying requests, amending protocol repeatedly, and monitoring longitudinal parameters (linkage) offer a flexibility that is difficult to achieve through conventional studies.

Limitations and recommendations

Limitations

The appeal of these new tools and data sources is nevertheless greatly limited at the moment by two factors: first, methodological limitations, and second, regulatory and ethical impediments. The suggestions and recommendations of the round table were formulated based on these two distinct aspects of the issue.

Methodological limitations

There are numerous methodological limitations for this type of research. The first limitation is a counterpoint to the advantage listed above that the data is spontaneously and sincerely provided by anonymous patients (typically using a user name or alias) and calls into question the veracity of this declarative data. At worst, these statements may be completely made up (''On the Internet, nobody knows you are a dog'', the New Yorker, 1993). In an environment where quality, data testing, and checking sources are all extremely important, this fact may seem prohibitive. It would therefore be useful to know the truth about these ''false'' patients using different types of media. The problem probably varies depending on the number of patients

studied and whether or not the online patient communities in question are structured and administered or if they are blogs, forums, and social networks.

Another limitation to this type of declarative data is the lack of medical confirmation, complicating issues including distinguishing between an adverse event and an adverse reaction. However, some subjective data currently collected as part of traditional clinical trials raises the same issues.

The difficulties interpreting and classifying these statements and sometimes the language barrier if the tool is multilingual, as described above, are major challenges for using this data for research.

Despite the large number of people in these communities, there are multiple potential biases in the representativeness of these groups. People's tendency to turn to digital media, the web, and social networks varies widely depending on their age, sociocultural and professional characteristics, and lifestyle, and on whether they live in an urban or rural setting. A keener understanding of the populations of communities being studied is necessary to potentially be able to correct these biases.

The influence of the environment, particularly the media [31], and how well-known a question is within a community should not be neglected. Researchers must take into account these factors when analysing the incidence of an event, when identifying relevant key words and when detecting, understanding, and processing the amplification of a sign.

In the case of forums, they sometimes stray from the initial topic, drastically decreasing usable data once the thousands of discussion threads that are empty or off topic are filtered out.

One of the other main methodological limitations of using online patient communities relates to the diversity of structures of various media because of their differing goals. For example, there are websites, forums, commercial platforms, and associative communities dedicated wholly or partially to patients or even not focused specifically on them.

One of the major obstacles reported is also the variety and lack of interoperability of semantic lexicons and glossaries used for medical terminology (UMLS, systematic nomenclature medical clinical terms [SNOMED], multi-technologies health server [SMTS], etc.).

Finally, from a research perspective, the inability of researchers to view certain communities and networks, particularly very closed-off communities for patients only, and the issue of paying for access to some of the more structured commercial platforms is regrettable.

Ethical and regulatory issues

In addition to methodological limitations, there are ethical questions and an almost total absence of or conversely incredibly complex regulations on certain aspects. This situation is undoubtedly due to the innovative nature of the subject.

Can security, anonymity and confidentiality always be guaranteed for data provided by patients? How can we guarantee that the patient is aware of and consents to the use of their data and that the way the data is used is transparent?

The issues of data accessibility and data ownership (as a reminder, we are talking about personal information that has been made public) add a level of uncertainty for researchers. These issues are similar to those encountered in the fields of big data, open data, and data warehouses, and in the use of hospital databases for research. However, this uncertainty is reinforced because of the spontaneous — and even candid and naive — nature of statements and information provided by patients. The question comes down to this: *to whom does patient data belong?* To be more precise: *to whom does data that patients post on the internet belong?*

Powerful tools already exist and technology is progressing rapidly. Digital robots can already take in and study entire forums and blogs and hundreds of discussion threads. There is therefore an urgent need to clarify these ethical questions researchers are asking. Very recently, two French projects employing these technologies have made the news. The first project, Vigi4Med, was a publicly-financed effort to create resources for finding, filtering, and analysing patient comments on certain drugs on the internet and carry out a retrospective and prospective assessment of this information [32]. The expected costs and benefits of proactive research into warning signs on the internet could also be measured. The second project, ADR-PRISM, was conducted by a public-private consortium and financed by a single inter-ministry fund. It had similar goals in the field of pharmacovigilance [33].

Finally, since we are examining clinical research and studies in real-life usage conditions, questions arise concerning whether competent authorities will recognise and accept this data when it is not possible to verify data and check source medical files for patients since these sites generally guarantee anonymity.

Given these main methodological, ethical, and regulatory limitations identified, the round table worked to draft a number of recommendations.

Suggestions and recommendations

The methodological suggestions and recommendations of the members of the round table are aimed primarily at researchers and professionals in this sector, while the regulatory recommendations are primarily meant for health authorities and policy makers.

Methodological recommendations

The first recommendation is to list and describe available resources. This description should make it possible to consider these resources based on their declared themes and goals. It should also aid research by laying out the number of members, visitors, and communities, the characteristics of available data and whether external researchers have access to them, the structure of bases and the computer languages used, internal statistical and digital expertise, etc.

An effort of this scale cannot be successful without the support of public authorities and/or without pooling the resources of several public or private stakeholders. As there will predictably be ongoing evolution to websites open to patients and caregivers, regular updates of this public directory should be planned in advance.

The round table recommends implementing a reference system of cohorts from online communities and networks

(''web cohorts''), in the Portail Épidémiologie France along-side more traditional cohorts formed by researchers in order to provide better visibility to these groups and strengthen their advantages.

To continue progressing in use of these tools and to address the known difficulties of interpreting and classify-ing the exact words of patients and dealing with language barriers, researchers and other professionals must work to create glossaries and lexicons of language used by patients and align each term with a reference terminology. Ide-ally, this reference terminology should be integrated into a multi-terminological server like the UMLS (with its known limitations in French) or in unifed medical lexicon for French (UMLF) [34] or French multi-terminology indexer (FMTI) [35].

To deal with methodological difficulties and the het-erogeneity of approaches and media, professionals and researchers should agree upon best practices for collecting and analysing data from online patient communities and networks (both quantitative and qualitative approaches). These could be formalised in a methodological guide or spec-ifications manual. To this end, it would be very interesting to follow the progress of the Vigi4Med project that aims to produce recommendations for the best way to use patient comments in forums for research.

Ethical and regulatory suggestions and recommendations

The rights of patients involved in research must be guar-anteed. Once again, writing a guide of best practices for use of personal e-health data from online patient commu-nities for research would help fill in gaps in the current regulatory framework. The following should specifically be addressed: information on the support structure of the com-munity, use of health data collected, recommendations for users to avoid the inherent risk of sharing personal infor-mation in public spaces, access by third parties, scope and temporality of consent, calls for sharing the research pro-cess and access to results obtained [36].

More specifically, for biomedical research, a joint task force with the national conference of institutional review boards (IRBs) would make it possible to ensure proper con-ditions for carrying out these studies and sharing knowledge from different types of research carried out within online patient communities.

For pharmacovigilance, notifying public health authori-ties of an adverse effect traditionally requires knowing an identifiable source (the notifier), an identifiable patient, the name of the product suspected of causing it, and the nature of the adverse effect. Once many kinds of teams of researchers begin mining data from platforms with several hundreds or thousands of patients, sorting through thousands of conversations in blogs or forums, the probability of discovering information concerning adverse effects that could increase our body of knowledge in pharmacovigilance for a health product, or even gen-erate potential warning signs, could greatly increase. Ideally, all stakeholders (ANSM, pharmacovigilance centres, patient associations, and researchers and pharmacovigi-lance experts in the industry) should come together to consider how to act in these situations.

For French and European health authorities, establishing admissibility conditions for PRO/PRI in regulatory studies is an essential step for promoting biomedical research stud-ies in the scientific and medical community. To date, only a single panel with an FDA representative, a representative of online patient communities, and industry members has meet to consider these issues [37].

Conclusion

The digital revolution and the extreme shift it has brought about pose an unprecedented challenge for the commu-nity of researchers examining health products by multiplying the amount of information available. This information and patient data can help support clinical, epidemiological, pharmacoepidemiological and pharmacosocietal research. Of the numerous existing digital platform models, some have more resources for carrying out this research and can produce results of adequate quality for publication in well-renowned scientific journals. These media provide patients with an opportunity for actively participating, belonging to a community, and gaining knowledge through a network of peers, thereby putting the focus of research back on patients. Researchers must in turn guarantee the quality and relevance of their research that uses the patients' per-sonal data. Modernising research on health products is a critical challenge given how difficult, complex, and costly it currently is to continue to improve progress in find-ing treatments. The insights of the round table are also encouragement to continue considering these issues so that research develops ethically and responsibly and to promote the initiative of academic and patients associations as well as economic actors who are indispensable to creating value and innovation.

Disclosure of interest

Mr Michael Chekroun, co-author of this publication is presi-dent and founder of the company Carenity.

The other authors declare that they have no competing interest.

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