

**UNLOCKING
THE FULL POTENTIAL
OF DATA ANALYTICS
FOR THE BENEFIT
OF ALL**




NOVEMBER, 2015



**HEALTHCARE
DATA INSTITUTE**

INTERNATIONAL THINK TANK
DEDICATED TO BIG DATA IN HEALTHCARE







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THE HEALTHCARE DATA INSTITUTE

EXECUTIVE SUMMARY

Although current debates on healthcare data often focus overly on potential risks and misuses of the data, benefits to be reaped from extending healthcare data usage are in fact immense. A multitude of use cases are there to prove the extensive value being created by data analytics, across all stakeholders of the healthcare system, including patients, healthcare professionals and providers, payers, researchers, biopharma and medical device companies, regulators and healthcare authorities.

Yet, despite all the potential benefits, significant obstacles to a wider use of healthcare data analytics remain in many systems. The four main barriers observed in France provide with a good illustration: (i) limitations to the collected data, (ii) barriers to the fluidity of data access and circulation, (iii) lack of focus, investment and fragmentation of innovation efforts, and (iv) resistant mindsets (notably from healthcare professionals) and a somewhat obsessive focus on risks.

Taken together at the level of a healthcare system, four major actions could provide a “framework for action” to address these barriers and accelerate the use of analytics across many systems, including France:

- Modernizing data infrastructure, management and access, for instance by creating a cloud-based, open infrastructure managed by a dedicated operator,
- Stimulating innovation at scale, potentially through further research funding, the creation of an innovative “cluster” of world-class excellence in healthcare analytics able to attract at scale talent and public/private investments, easier access to early-stage funding and to public tenders, and further public-private collaboration,
- Creating new incentive mechanisms to support a shift in mindsets, such as episode-based and outcomes-driven performance payments or even capitation-based models, which all reward the value of care provided rather than volume,
- Simplifying the legal frameworks.

More work is now needed to design effective and operational solutions across and beyond these four areas. The potential impact on improving both quality and financial sustainability of health systems will be well worth it.

LEVERAGING HEALTHCARE DATA ANALYTICS FOR THE BENEFIT OF ALL STAKEHOLDERS IN THE SYSTEM

Recent discussions about opening access to healthcare data in France have shown that the dialogue around the use of health data is often confused and incomplete.

First, imprecise language confuses the discussion. The terms “Open Data,” “Big Data”, and sometimes “Smart Data” are often used interchangeably, though they designate distinct concepts:

- “Open Data” refers to data -- in this case health data -- that is made available to others, ideally in a format that facilitates re-use without restrictions from copyright, patents or other mechanisms of control.
- “Big Data” refers to data that is so voluminous and fast growing that it is potentially extremely valuable but difficult to analyze with conventional tools. The information contained in the wealth of available biomedical publications, data from genome sequencing, or reimbursement data such as the SNIIRAM database in France (which collects claims information across primary and hospital care at individual patient level) are just a few examples.
- Finally, fully harnessing insights from specific data (“Smart Data”) can often bring significant benefits, without having to rely on massive amounts of “Big Data”.

Second, current debates on healthcare data often focus overly on potential risks and misuses of the data. Furthermore, despite the variety of potential use-cases and benefits of healthcare data, stakeholders in the discussions often focus on a portion of the benefits, leaving aside elements that are nevertheless essential for informed decision-making.

Therefore, though it would be impossible to cover all the benefits of further leveraging healthcare data, it is worthwhile to outline key benefits that greater and smarter use of data analytics can bring to the main stakeholders of a healthcare system: patients, healthcare professionals and providers, payers, researchers, biopharma and medical device companies, regulators and healthcare authorities.

Applying advanced analytics to healthcare data offers great potential to create more value and improve our healthcare system by: 1) accelerating innovation, 2) improving decision-making, 3) fostering productivity and effectiveness, and 4) improving democratic oversight over the system.

1 PATIENTS: ACCESS AND MORE



Historically in discussions of the use of big data, patient associations have focused on the potential risks linked to abuses of personal health records (such as predicting individual or family health risks and the negative consequences on insurance premiums and eventually access to care). Gradually, however, patients have been coming to embrace the many benefits healthcare data analytics can provide, while still keeping a watchful eye on potential risks linked to abuses in how the data is used.

In fact, citizens (and patients) have shown a growing willingness to share their personal data even beyond their designated care professionals. A recent survey conducted by Odoxa on behalf of Orange Healthcare and MNH in France showed, for instance, that French citizens are willing to share their personal health information not only with the professionals taking care of their health (86% agree), but also with other healthcare professionals (79%) and even with trusted third parties they would choose (74%).

A wider and better usage of healthcare data analytics can provide benefits to patients by accelerating medical progress and innovation in care without compromising – and in fact enhancing – access to care, patient empowerment, and the human element in the relationship between patients and professionals:

- **Improving access to care:** In many systems today, a lack of transparency and asymmetries of information – arguably more than financial means – lead to inequality of access to care. Well informed and connected people are able to seek the best experts and potentially get the best advice and treatment. In many countries, including France, the need for the patient to be physically present in front of the physician also leads to inequalities in timely access to the best specialized advice. The sharing of healthcare information could bring significant benefits for patients in both these cases. They could also benefit by getting information on diseases and treatments through websites such as NHS Choices in the UK or Doctissimo in France, or by seeking the best place for treatment based on quality metrics (examples like Healthgrade leveraging Medicare data abound in the US) or time to appointment (like the Norwegian information service <http://www.frittisyrkehusvalg.no>, “Free Hospital Choice Norway”).
- **Allowing patients to take control of their health and get customized advice and care.** Increasingly, a number of applications relying heavily on healthcare data analytics are available to support patients in managing their condition (e.g., better understanding it, influencing their own medical care), and/or in getting evermore targeted and relevant medical care. Data-enriched tools, applications and algorithms are being introduced daily. These include personalized and shareable electronic medical records (the famous *Blue Button*); decision-supporting tools, such as Indigo’s Archimedes, to influence lifestyle/ behavior choices and/or select the right treatment, or online services or smartphone apps (such as www.drugs.com) helping patients identify potential contraindications or the risk of drug-drug interactions; remote services combining an avatar-based interface with movement recognition technology and a link with IBM’s Watson to support decisions and answer patients’ questions (such as iDAvatar), and many others. To some extent, the willingness of patients to adopt such tools could appear as counterintuitive, since patient associations often voice a concern about a risk of “dehumanization” of healthcare through a potential replacement of health professionals by machines, which analytics could encourage. However, provided that artificial intelligence and human intelligence work together, data analytics offer a wealth of opportunities to further individualize medical approaches and could actually allow the medical professional to focus more on the human element of his/her relationship to the patient.
- **Providing transparency for better oversight by citizens.** As more information is made available to patients and patient associations (and more broadly to citizens whether they are patients or not), and as greater transparency is created on how healthcare is provided, the ability of citizens to influence policy-making and hold stakeholders accountable for their actions is greatly enhanced. Patient associations increasingly consider data and analytics as critically valuable tools, which enable them to further influence policy-making, as the Renaloo example below illustrates.

ENABLING FACT-BASED PATIENT ACTIVISM AND INFLUENCE

THE RENALOO EXAMPLE IN CHRONIC KIDNEY DISEASE

Renaloo, a French patients’ organization dedicated to people with chronic kidney disease (CKD), kidney transplant and dialysis, issued a first study in 2013, based on data from the French kidney register, which includes over 10 years of historical data for all end-stage renal disease (ESRD) patients in France, and additional data collected through a dedicated survey. The study aimed to highlight disparities in treatment and, in particular, in the access to kidney transplant, which provides improved quality of life and life expectancy to patients and lower costs to the system (being much cheaper than dialysis, which concerns 55% of ESRD patients and represents over 80% of the ~€4bn spent annually on ESRD).

Initial conclusions of the study highlighted major disparities in access to treatment, both geographically and socially, which cannot be explained by organ shortage alone. Dialysis patients are noticeably less educated than transplant patients: after age adjustment, more than 75% of dialysis patients have less than a high school education, compared to about 40% of transplant patients.

The study has helped influence and shape national and regional healthcare policies. For example, CKD has been put forward as a pilot pathology nationwide for the improvement of care pathways and experimentation with new financing mechanisms.

www.renaloo.com

2 PROFESSIONALS AND PROVIDERS: MORE THAN DIGITALLY ENABLED PROCESSES



Many care professionals, sometimes citing “the art of medicine”, still resist the drive towards more transparency, the evaluation of practices, and data-driven decision-making. Yet a number of striking examples (see Kaiser Permanente vignette below) highlight the benefits of an approach leveraging healthcare data and combining the digitalization of some core processes with systematic evidence-based protocols of care.

KAISER PERMANENTE

EVIDENCE-BASED PROTOCOLS DRIVING CARE, BASED ON STRUCTURED PATIENT REGISTRIES AND A DIGITAL BACKBONE

Kaiser is an integrated HMO system which provides healthcare coverage and care to over 10 million people across several states in the western part of the United States. Over the last 20 years or so, they have been able to move from a middle-of-the-pack integrated system in terms of care quality and management to one of the reference systems in the US and globally.

Establishing such a high quality and financially sustainable system has relied notably on:

- Mining and harnessing insights from systematic large-scale patient registries/cohorts across key disease areas,
- Driving evidence-based care protocols and leveraging insights from the healthcare data collected,
- Investing several billion USD in an electronic Health Record (eHR), which allows the system to drive clinical practices, collect clinical information and other data on an individual patient basis, and optimize the interfaces between patients and professionals.

www.kaiserpermanente.org

In fact, leveraging healthcare data can provide a wide range of benefits to healthcare professionals, notably physicians and providers, which by far outweigh (at least for the strong performing ones) the risks linked to stronger transparency and evaluation:

- **Better assessing and optimizing treatment protocols and care pathways.** Healthcare data analytics can enable providers to significantly improve decision-making on several accounts. Among the most critical decisions are obviously the design of the right treatment protocols and the choice of adequate treatment for a given patient:
 - To deliver the best possible care at the right cost, providers must be in a position to adequately assess the relative performance of different treatment protocols, the potential of even individual treatments or products, innovative or not. For example, a systematic statistical evaluation of post-operative complications linked to different post-surgical protocols typically yields critical insights in deciding which techniques can be adopted as general practice, adapted, or even abandoned to improve outcomes. Currently, these protocols evolve quite rapidly, and few providers formalize and evaluate them in terms of health outcomes. In addition, deciding on protocols or technologies often drives significant investments. For instance, understanding the future place of brachytherapy (also known as curietherapy) vs. surgery in the treatment of prostate cancer will influence significant investment decisions.
 - Increasingly, treatment decision-making tools are becoming available. Algorithms comparing a patient’s clinical (and other) data with large datasets and leveraging all the existing scientific literature provide increasingly precise support to the crucial medical decisions of diagnostic and treatment choices. As the number of diagnostic tools (such as imaging and “omics” sciences) continues to expand and as the sum of all biomedical scientific literature doubles every 5-7 years, more initiatives such as IBM’s Watson, Akelex, and Indigo’s Archimedes, will continue to emerge.
- **Guiding the (re)configuration of care provision to meet specific needs of a given territory.** Typically, medico-administrative data (such as claims) can help assess and understand healthcare needs in a given territory. For instance, it can allow acute care hospitals and other healthcare

institutions to identify which professionals provide care to their patients in the community and understand competitive dynamics. This in turn allows the institution to identify and target community professionals and other care institutions with whom to strengthen their relationships and cooperate further (e.g. for patients requiring care across multiple care settings, such as geriatric patients). This data can also help an institution to decide on which portfolio of services to offer.

- **Innovating in patient care and services.** In combination with new technologies, data analytics can help care providers extend care pathways and services “beyond their walls” (provided that payment mechanisms generate an adequate business model). For example, new measurement technologies (such as wearable, ingestible or implantable sensors) can transmit data that will allow a provider to head off a patient crisis. By monitoring vital signs of its diabetic patients, for example, a provider may be able to anticipate and prevent complications such as diabetic foot and avoid amputation. In patients with psychiatric or neurological conditions, precise monitoring of a combination of indicators can improve predictability of a crisis. An increasing number of continuous monitoring services, relying notably on connected objects and data analytics, are already transforming care for chronic patients. Examples include Bioserenity solutions for epilepsy, Ginger.io for chronic conditions, several congestive heart failure programs in Germany, or Diabeo for individualized insulin dosing.
- **Competing on quality.** Publishing open data on quality of care could allow to orchestrate competition among providers based on quality of care and could be a major lever to increase overall quality across the system. Obviously, that implies reliably monitoring quality of care data (and not just claims), and establishing the right analytical tools to provide meaningful comparisons, adjusting for instance to differences in case mix and patient profiles (which analytics approaches can again effectively support).

The use of data analytics described above will likely have a profound impact on healthcare professionals. For example, a continuous remote monitoring service which regularly transfers a synthesis of a patient’s recorded parameters and alerts a physician of a potential anomaly would greatly reduce the need for the traditional consultation (and lead to a loss of revenues for the professional in a fee-for-service payment model). Such applications already exist in diabetes care, in chronic heart failure or postoperative follow-up, just to name a few. The initial reaction of many professionals has, understandably, been to resist such profound change. To shift provider mindsets will require proactive action by healthcare authorities and aligned incentives.

3 PAYERS: THE RIGHT TREATMENT AT THE RIGHT PRICE



A principal goal of payers, especially statutory health insurers such as l’Assurance Maladie in France, is to finance healthcare providers efficiently while ensuring that care is effective, administered with a sufficient level of quality, and administered only to those persons who need it and can benefit from it.

The increasing comprehensiveness and specificity of healthcare data have drastically increased the ability of payers to develop data-driven approaches to optimize the quality and efficiency of care pathways, drugs, devices and services. Claims data collected to administer payments (for example, the precise coding of medical procedures, hospital stays, and drugs prescribed/ dispensed), and the ability to link that information at an individual patient level (either anonymized, pseudonymized or not) make it possible to better manage healthcare demand, shape more effective risk-management programs, drive improvements in provider performance, and work with regulators to assess health-economic efficiency of treatments:

- **Managing demand for healthcare services by creating value-conscious and empowered healthcare consumers.** Data analytics and transparent information can make patients conscious of the value and cost of their care. Thanks to new technologies, patients have at their disposal rich information about illnesses, treatment, and payments that can help them shape their

own care pathway based on objective and verified criteria and better understand and control their health expenditures. For instance, websites such as *Annuaire santé* (ex Ameli direct) in France allow individuals to verify health practitioners' services and prices. With the help of a data-based tool, a German payer identified the potential to reduce by over 3% the number of hospital admissions resulting from adverse drug interactions. Greater transparency, with tools such as NHS Choices in the UK, also enables patients to find their way into the healthcare system and helps them select the therapeutic approaches that best fit their profile and meet their individual needs.

- **Designing more effective risk management programs by segmenting patients and stratifying risks.** Data analytics make it possible to assess deviations from protocols by region and individual provider (for instance in looking at the rate of pre-scheduled caesarian cuts across providers, or the rate of prescription of antibiotics by physician). Healthcare system effectiveness can then be improved by targeting programs and actions at patients and providers/professionals who deviate farthest from protocols or who are more likely to change behavior.

Data analytics can also be used to build predictive models and segment patients based on their healthcare risk, to tailor treatment protocols to their profile. Such models are critical to the success of disease management programs. In the French *Sophia* diabetes disease management program, for example, data analytics make it possible to identify patients who did not undergo recommended tests and are therefore most likely to benefit from the program. The *Prado* hospital discharge optimization program can identify patients who are likely to present complications, making it possible to differentiate patients who will need “step-down” services after hospital discharge from those who can do their rehab in the home setting. Another way of leveraging analytics to reduce costs is by better predicting future patient needs and designing plans/programs that are adapted to the risk level of each segment (also taking into account marketing and operational costs). As an example, Predilytics offers payers in the US predictive models based on genetic algorithms and demographic and clinical data from 140 million households, which have made possible double-digit reductions in the costs of customer acquisition, retention and conversion for payers.

- **Driving improvements in performance and efficiency of both individual providers and healthcare systems.** For example, in healthcare systems which are still lagging in adoption of outpatient/ same-day surgery (such as France's), analysing care practices across providers can allow payers to identify poor performers and target specific actions to accelerate adoption (such as requiring those providers to obtain prior approval from the payer to perform an in-patient procedure when an out-patient alternative exists). In another example, Lumeris leverages data to support new models of contract management between payers and providers in which have resulted in ~30% cost reductions for payers and ~40% reduction in readmission rates.
- **Assessing treatments to enhance health-economic efficiency.** Data analytics are a key enabler for evidence-based medicine. A prominent example is the unveiling of the cardiovascular safety issues linked to Vioxx in 2004, which was based on analysis of data from a registry of 1.4 m Kaiser Permanente patients. In France, l'Assurance Maladie has more recently leveraged analytics to evaluate the impact of various statins and has been driving several performance-improvement measures (such as requiring prior payer approval for any Rosuvastatin initiation and including KPIs linked to statin prescription behavior in GP's pay-for-performance scheme).

4 LIFE SCIENCES: TOOLS TO ACCELERATE RESEARCH



With the rise of digital technologies, life sciences and healthcare stand on the threshold of a revolution. The development of global and rapid analysis methods initiated with genome sequencing (genomics, proteomics, metabolomics,...) but also the increasing digitalization of numerous information (medical, cohorts, populations, biological,...) now generate considerable amounts of data. The exploitation and analysis of these big data generates new opportunities, and help address technological, scientific and medical challenges.

- **Improving early diagnostics by pooling information to identify new biomarkers:** With the use of appropriate analytical tools, the available big data will bring out signals – today unfathomable – that will be relevant biomarkers for certain diseases. Some such tools are currently emerging. For instance, the *Centre d'acquisition et de traitement d'images pour la maladie d'Alzheimer* (CATT) has established a network of fifty MRI and PET imagers, spread all over France, which is transferring images to a centralized database. Once the data are collected, analyzed and combined with other clinical data, they are subject to data mining tools in order to identify relevant biomarkers. The aggregated data provides a diagnostic aid that will be enhanced as the data accumulate. The center, initially dedicated to dementia, has since expanded its activities in research projects or therapeutic trials relating to other brain pathologies.
- **Refining the understanding of chronic pathologies:** The combination of clinical, “omics”, and health data has already helped identify subgroups within pathologies that were hitherto considered homogeneous¹. The aggregation, combination and analysis of multiple and heterogeneous data, using new mathematical models and biological modeling, allows researchers to go even further. The paradigm that linked a gene, a protein and a function can be revisited in the light of “omics” tools. Many biological mechanisms now show networks of interaction with interlocked control systems that can be redundant. Big data foster a new way of understanding biology. They offer the opportunity to obtain and analyze very large volumes of multi-scale data (molecular, cellular, tissue, environmental) by which new relationships between multiple variables can be identified. Their correlation will feed increasingly detailed models of life phenomena. The connection of these models and the processes described in basic research with biological, medical, behavioral or environmental data (genomics, transcriptomics, proteomics, metabolomics, microbiome, etc.) will bring out relevant biomarkers of pathologies and new ways to understand diseases on a molecular basis.
- **Accelerating the discovery and development of new drugs and therapies, at every stage of the R&D process.** These new models, alongside with a number of other analytical tools and approaches will bring a new paradigm for drug discovery. Computer-enabled evaluation of very large numbers of compounds, or drug virtual screening, allows to identify the structures which are most likely to bind to a drug target and speed up discovery. Toxicity prediction analyses allow to determine potential toxicity problems earlier, and therefore minimize late drug failures (in late development or even in clinical trials). Predictive modeling of biological processes helps to optimize clinical trial from start through close, and trial design optimization analysis allows to identify the right patient for the trial and optimize recruitment (e.g., leveraging Electronic Medical Records). Biomarkers make it possible to identify early in a drug's development patients who may respond better to treatment, and select those for which it will be the most effective once the drug is on the market. And these are just a few examples.

5 BIO-PHARMA: THE DAWNING OF NEW VALUE PROPOSITIONS



Life science companies are finding many benefits in entering more fully into the age of healthcare data analytics, whether they operate in the area of drugs or medical devices:

- **Facilitating drug/ device evaluation.** The use of medico-administrative databases can, in specific cases, provide a more effective way to address the requirement for real-life data following the reimbursement of drugs or devices in order to maintain reimbursement over the years. Generating such data through post-marketing trials is a long, costly process and is often ineffective. A study under way in France to evaluate 5 carotid stents introduced in 2009 (by 5 different companies) leveraging the SNIIRAM claims data is a good example of using a medico-administrative database as an alternative. When a post-reimbursement registry measuring the cumulative morbi-mortality rate at 30 days of implanted patients failed to gain interest from clinicians, the SNIIRAM data was accepted by regulators (HAS and CEPS in this case) as an alternative.

¹ See Stephen T. Holgate, “Stratified approaches to the treatment of asthma”, *British Journal of Clinical Pharmacology*, vol. 76, n°2, 16/11/2012 (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3731602/>)

- **Enabling the development of personalized medicine:** As data become richer and more accessible, analytics promise to help drug developers define and predict those patients who will best respond to a particular drug. They can analyze thousands of indicators per patient in the context of clinical trials, by accessing more data about patient profile, past history and patient condition during the trial. Larger data volumes and improved analytics also pave the way to more opportunities for personalized medicine. Though targeted therapies have shown considerable progress in the way we treat cancers, they are still confined to a limited population. The WIN consortium (Worldwide Innovative Networking in personalized cancer medicine), an alliance of some of the best oncology centers worldwide and industrial partners, may be emblematic of things to come for the industry. WINTHER, a clinical trial conducted in the consortium's centers, aims at introducing algorithm-based tools to select the potential best treatments for every patient. As explained by the Win Consortium, "*Winther represents a breakthrough concept to match tumor biology and therapeutics in individual patients. Today, such matches are usually made by testing DNA from tumor biopsies (testing for mutations, translocations, CNV). However, this approach benefits only 30-40% of patients.*"²
- **Fostering the emergence of a new era of data-assisted decision-making:** As the WINTHER trial illustrates, the next era could be one where data-assisted decision-making in clinical settings might become the predominant determining factor for market access, rather than, as used to be the case, promotional efforts (including notably Medical Reps or Medical Science Liaisons) or, more recently, Health-Technology Assessments. Data analytics can thus become an integral part of treatment that could both change the outcomes for the patient and reduce waste in resources by helping prescribe the right product at the right moment. Analytics would also potentially improve safety by decreasing diagnostic and prescription errors. Another consequence of these developments is that by getting a better understanding of what is needed for each patient and being able to predict the outcomes and monitor them in real life, new opportunities like risk-sharing schemes between pharma companies and payers could emerge. Reducing the uncertainty and risk often associated with risk-sharing arrangements could dramatically change their attractiveness. One example is Fibrotest, a non-invasive assessment of liver fibrosis developed at Assistance Publique – Hôpitaux de Paris (AP-HP) in chronic hepatitis C and B. This alternative to liver biopsy is now recommended as first line for the assessment of fibrosis in untreated chronic hepatitis C and its reimbursement value, based both on the measure of the markers and the algorithm that processes them to give the test result.
- **Contributing to a “data-enriched” daily life:** The use of healthcare data can significantly enhance the value and convenience of many treatments. For instance, models by pathology are already emerging, which make it possible to develop much more precise tracking and monitoring tools, in particular for chronic diseases, such as diabetes (see Diabeloop vignette), drastically improving the individual management of his/her disease by the patient and healthcare professionals. More complex models are on their way.

THE DIABELOOP PROJECT

The Diabeloop project (Ceridit, CEA Leti) is developing an artificial pancreas to improve treatment for Type 1 diabetes patients. The research team is developing algorithms which, once embedded on a smartphone and coupled with blood glucose sensors and an insulin pump, are able to control the entire system and adapt to the patient profile and activity. The originality of such system lies in its ability to clinically manage unpredictable variability of blood glucose rather than the average basic needs that are usually fairly well defined.

The Diabeloop system should fundamentally improve the everyday life of diabetes patients, allowing better control of their blood sugar and substantially reducing hypoglycemic events and associated comas, as well as decreasing diabetes-related complications, such as ocular and renal complications and amputations.

Diabeloop will also exploit both real and simulated data to improve insulin physiology numerical models with a focus on how physical activity and emotional states affect glycaemia levels. Clinical trials involving patients living at home are expected at the end of 2015.

www.diabeloop.fr

² <http://www.winconsortium.org/>

Besides the direct benefits for the patient, health management programs may also well represent what is developing right now: enabling the patient to be in an environment closer to a clinical trial than ever before. By controlling many factors that would impact treatment outcomes (such as compliance and other issues), this type of program can support industry players that need to deliver the value demonstrated in clinical trials. The use of health data analytics will trigger a significant leap in better health management and help close the gap between clinical trial results and real life outcomes. One example is the Sympad program launched by MédecinDirect, a company providing access to healthcare professionals through the web or over the phone.

CONTRIBUTING TO A DATA-ENRICHED DAILY LIFE

THE SYMPAD EXAMPLE

Sympad is a project supported by MédecinDirect which brings together MADoPA partners Assisteo, 2CSi, CEA Leti, ArianaPharma and Telecom Bretagne. Based on the communication system developed by BostonLifeLabs (including Hbox for the communication hub), Sympad offers an innovative approach for collecting medical data both in pharmacies and at the patient's home.

Sympad is a pharmacy-based remote monitoring system for patients with chronic conditions, which uses algorithms to identify signals associated with complications and to trigger further medical supervision. It improves the management and monitoring of chronic patients by pharmacists by optimizing patient monitoring and home pharmacy, allowing prevention screening at the pharmacy, and strengthening the pharmacist in his new assignments. It consists of a multi-user and multi-function measurement unit that collects all the relevant data, combining the measurement of clinical parameters and the monitoring of the patient's general health condition (weight, blood pressure, respiration, etc.), coupled with patient questionnaires, adherence to drug prescriptions, and pharmacovigilance. Sympad produces real-time analyses and issues opinions and recommendations through its medicalized and secure platform, MédecinDirect.

www.sympad.info

Beyond the progress towards choosing the right treatment at the right time, this evolution means more value shifting to data volumes, data quality, data access and data analytics.

6 HEALTHCARE AUTHORITIES: ENHANCED MEANS OF REGULATION



National or regional healthcare authorities (Ministries of Health, regional health agencies) and regulators (such as HAS and ANSM in France, and NICE or Monitor in the UK) can also capture significant benefits through mining and leveraging the richness of healthcare data to achieve improvements in quality, safety, accessibility and cost efficiency of the healthcare system. Among the many different benefits, some of the most notable are:

- **Improving decision- and policy-making by leveraging a deeper and more easily “digestible” fact base, for example by:**
 - **Evaluating health status of the population and informing the planning and reconfiguration of healthcare services** (e.g. restructuring/ reallocating care provision across a region): Data analytics can reveal the local needs of the population, socio-demographics, epidemiology, risk factors, geographical distribution/ travel times, current quality of care and outcomes and other data, all at a granular level. Many emerging tools make it easier today for policy-makers to make fuller use of the available information, and in particular to find easy ways to analyze huge masses of information. As an example, services/tools such as Palantir (www.palantir.com) greatly facilitate cross-analysis and display of information from various sources, such as the incidence of a given disease, the availability of treatment, the average size of providers, and the clinical outcomes per area.
 - **Improving detection and interpretation of early/ weak signals in public health surveillance.** With the ability to process large amounts of information in real-time, social

networks and other alternative data sources become a precious source of insights. Correlating adverse events with information from social networks can, for instance, provide powerful means to analyse and anticipate such events. The ADR-PRISM project (<http://adr-prism.com>) led by Temis and Kappa Santé, which mines non-structured text information from community websites to track adverse drug events is a good example of leveraging social networks for pharmacovigilance purposes.

– **Defining and managing payment systems:** Innovative systems, such as episode-based tariffs and/or outcome-driven payment system across several steps in the care continuum, require collection of individual patient data across healthcare providers and analysis of health economic outcomes. The Arkansas Health Care Payment Improvement Initiative (www.paymentinitiative.org) for instance, leveraged analytics to model and track costs per patient across the most common pathways, across all care settings. This enables the definition of an acceptable corridor and application of a bonus/malus payment system if costs are lower or exceed the target cost corridor.

– **Evaluating new treatment protocols, drugs or devices:** With the increasing availability of data, many innovative approaches are emerging. In France, the recent publication by ANSM (the drug regulator) of a population-based study relying on claims data³ on the association between prosthesis characteristics in total hip replacement and reoperation rates illustrates the increasing use of database-driven approaches to assess and track impact of products or services. Many other policy decisions (including early warning signals and pandemic response) will also increasingly benefit from data availability and analysis.

- **Strengthening performance tracking and management of healthcare stakeholders by driving performance, in terms of quality, safety, accessibility or cost efficiency:** The availability of information and the resulting increase in performance transparency will create new rules of competition for players, driven either by regulators or by the patients themselves. In the US, the open publication of databases reporting outcomes (readmission rates, mortality, etc.) such as the HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) and the Agency for Healthcare Research and Quality’s Patient Safety Indicator, has led to the development of many information services, such as Healthgrades (www.healthgrades.com). How long will it take before we see the hospital equivalent of a TripAdvisor take as big a role in how patients’ choose a provider or a treatment?
- **Increasing transparency towards citizens based on open healthcare data:** Even though transparency is often perceived as risky, it can be a powerful tool to create alignment on a potential case for change. When NHS London conducted the “Healthcare for London” exercise (www.londonhp.nhs.uk/healthcare-for-london) that led to a fundamental redesign of the structure of care (including the reduction in the number of general academic hospitals, the creation of local “polyclinics”, and the redesign of several care pathways like stroke), sharing a thorough analysis of the actual state of health of Londoners was paramount to creating alignment behind some of the difficult decisions. Recently, the Institut Montaigne has shown that a better-informed group of citizens (25 citizens provided with a few days of information and briefing by experts on the challenges of the Healthcare system) is likely to propose some radical and needed changes (www.conferencedecitoyens.fr) to the system.

³ ANSM : Etude des facteurs associés aux révisions sur prothèses totales de hanche (PTH) : rôle du mode d’ancrage (cimentage) et des constituants prothétiques (couple de frottement) dans les révisions chirurgicales, May 2015

Given the significant benefits outlined above, these approaches in turn create significant opportunities for the development of value-added services, serving the analytics needs of the different stakeholders.

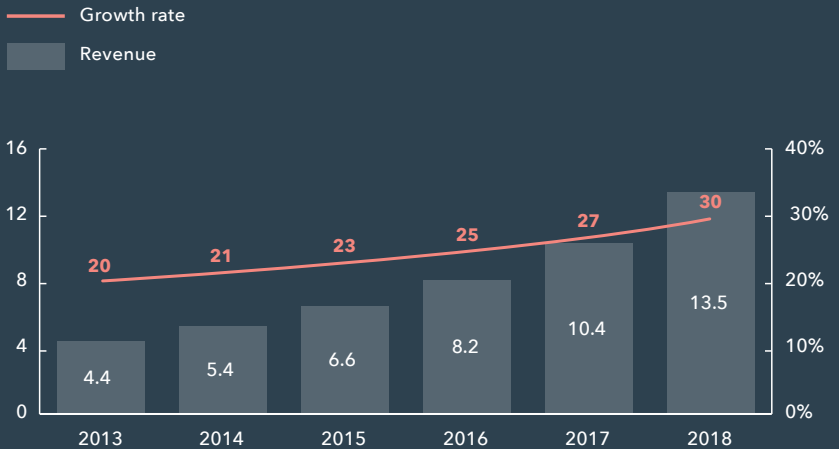
Over the last few years, this has led to the emergence of a significant business segment, which is expected to continue to grow significantly over the coming years in the US, in Europe, and across key geographies.

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The healthcare analytics market already represents over \$6bn and is expected to grow at 25+% annually over the next 5 years

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GLOBAL HEALTHCARE DATA ANALYTICS MARKET 2013-18, \$BN



SOURCE: Global Healthcare Data Analytics Market 2014-2018, TechNavio, released in Oct 2014

AT LEAST FOUR BARRIERS CURRENTLY HINDERING THE CAPTURE OF THE FULL POTENTIAL OF ANALYTICS

Despite all the benefits to be gained from healthcare data analytics, obstacles to a wider use remain, spanning issues of data quality, infrastructure, regulation and mindsets, as illustrated by four main barriers observed in France:

- **Limitations to the collected data.** While claims data (the SNIIRAM) is rich and comprehensive in France, a systematic and structured approach to collect data, in particular clinical data, is missing. A number of cohorts/registries do exist (e.g. Constances⁴), but they are too limited and too few, compared to systems like Kaiser Permanente in the US or even a number of Scandinavian countries or the General Practice Research Database (GPRD) in the UK, which aggregates anonymized data from medical records of ca. 5m patients. In addition, the quality and reliability of some of the collected clinical data remain sub-optimal – for example, in reporting of “adverse events” (“événements indésirables”) or even in recording simple patient data like BMI. With that respect, the lack of homogeneously applied standards and tools for clinical data collection is a significant limitation.
- **Barriers to the fluidity of data access and circulation.** The current legacy systems, most notably the SNIIRAM, were not designed to allow easy access and mining, which proves cumbersome even for the payer that manages the data (CNAMTS). In addition, the healthcare IT environment is very fragmented, and a lack of interoperability and communication protocols (e.g. multiple eMR/eHRs) hinders the ability to share and access data fluidly. Finally, the main barrier still is burdensome legal requirements and constraints, which exist primarily because of the need to protect non-anonymized personal data and a lack of flexibility concerning the reutilization of data for an intent different from that for which the data were originally collected. Unfortunately, constraints extend even to anonymized data. As an illustration of the resulting difficulties, it took 15 months of administrative and legal processes for the post-marketing study currently under way on carotid stents to be granted access to the SNIIRAM reimbursement database.
- **Lack of focus and investment; fragmentation of efforts.** While a large number of initiatives emerge, they are scattered across many stakeholders and are often subscale. In addition, there is still a relative lack of mobilization of talents across other disciplines (like mathematics) on life-science related issues. While healthcare authorities have started to focus somewhat on accelerating the efforts, they have also been unwilling to abandon the “competitive advantage” provided by their privileged access to the data. As a consequence, we have not yet seen a scaled push to drive the innovation agenda on expanding the data collection and, more importantly, supporting the emergence of further analytics services and innovations.
- **Resistant mindsets and a somewhat obsessive focus on risks.** The debate about expanding healthcare data access and the use of analytics – both in the public, and to some extent even among experts – is focused significantly more on risks than benefits. This focus is raising fears and favoring the “principe de précaution” (the “precaution principle”) which argues against proceeding with an initiative whose risks are unclear. This “principe de précaution” can thwart the taking of (measured) risks which is essential to the process of innovation. This general risk aversion, as well as the profound changes that healthcare professional can expect with the expanded use of analytics, create resistant mindsets, in particular in the absence of both a clear “change story” outlining the benefits and of adequate incentives.

⁴ www.constances.fr

REAPING THE BENEFITS OF HEALTHCARE DATA ANALYTICS: A FRAMEWORK FOR ACTION

Taken together, four major actions could provide adequate answers to the main barriers to expanded use of healthcare analytics across many healthcare systems, including France.

Modernizing data infrastructure, management and access

Legacy payment administration and other existing systems cannot support the dramatic expansion of data analytics required to capture the full benefits, and enabling easier access to the data will likely require adoption of a new, modern, data infrastructure. Could we imagine a model where the data is cloud-based, and administered by a dedicated operator, which role would be to:

- Collect and aggregate data from different sources (the payer’s claims data, patient registries, environmental/ non-clinical data, etc.), and foster the improvement to the quality of data collected (development of further registries, improvement of the quality of data collection...);
- Manage the data (e.g. linking different data sources) and cloud-based data infrastructure;
- Provide and manage access of third parties (scientists, enterprises, patients associations, providers, etc.) to the data;
- Offer patients a portal through which they could manage their informed consent and indicate to whom they grant access to their information (similar to granting access to contact lists or location information to mobile Apps).

Such an operator, which would in effect render a public service, could be either public or private. It would likely need to be under the responsibility of a public regulator, which would set a number of critical ground rules in terms of privacy/ security, identity management, access, etc.

Stimulating innovation “at scale”

The expanded use of healthcare analytics will profoundly transform the very nature of the medical profession. Diagnostic and treatment decisions will be augmented through algorithms, and establishing a strong position in this field could (and possibly should) be considered strategic at a country level. Some companies are already taking positions to be part of that future market: Google/Alphabet is now making major inroads into the healthcare analytics field, including introducing devices such as connected wristband for cancer detection or a diabetes-monitoring lens.

If access to large amounts of relevant data is a must, innovation in analytics/ algorithmic science will be at least as important, and a country like France should consider a range of potential mechanisms to accelerate this innovation, including:

- Investing further in the **development of patient cohorts and registries** and dedicating “research funding” to research projects meeting set criteria/ specifications.
- Fostering the **emergence of an innovative “cluster” of world-class excellence in healthcare analytics**, which could attract talents at scale, and be a magnet for public and private initiatives. In this respect, a mechanism such as the IHU (Instituts Hospitalo-Universitaires) could be considered. Such an initiative, beyond providing further funding for innovation, would also have to serve as a mechanism to bring dispersed initiatives – public and private – together and build scale.
- **Using public procurement processes/contracts more purposefully**, would also help accelerate the adoption and scaling up of already more mature approaches and services (those that can be already implemented), by offering them facilitated access to public tenders.
- **Improving the access to seed and other early-stage funding** – as is intended in the recently announced Franco-German pledge to accelerate European technology startup investment – would also, like in other fields, help accelerate the emergence of innovative players.

- **Establishing further public-private collaborations**, such as the Accelerating Medicines Partnership (AMP) between the US National Institute of Health (NIH), the Federal Drug Administration (FDA), 10 biopharmaceutical companies and many NGOs, which aims at sharing resources, expertise and data to identify and validate promising biological targets.

Creating new incentive mechanisms to shift mindsets

As already mentioned, a shift in the mindsets of many healthcare professionals will be required to fully capture the opportunities from healthcare data and analytics. This will imply a shift towards a more data-driven culture, and towards more continuous and transparent evaluation of professional practices.

Achieving such a shift will likely require the combination of supports and incentives, including:

- Changes in the initial training curriculum of professionals, and in particular in medical education.
- A clear “change story” outlining benefits and not just risks.
- Most importantly, new funding mechanisms that provide clear incentives for professionals and providers to adopt new behaviors, such as episode-based payments, outcomes-driven performance payments (using both hard clinical outcomes and patient-reported ones) and/or even capitation-based models such as the Alzira model in Spain (www.modeloalzira.es/en/bases-conceptuales). There, a private provider has taken overall responsibility to provide care for a given population based on a fixed payment per capita. Current models such as DRG-based financing and fee-for-service models reward volume rather than value and quality of care provided, and do not typically provide incentives for robust clinical data collection/transparency and collaboration across care settings.
- Active support, training and resources (including funding) to healthcare professionals and institutions to implement the tools required.

Simplifying the legal frameworks

There is an urgent need for establishing an adequate European framework on healthcare data collection and usage. The EU General Data Protection Regulation is slated to replace the 1995 EU Data Protection Directive beginning in 2018. The Regulation will very likely introduce new definitions such as data concerning health and genetic data, but without substantially altering the permitted uses in a health care context. For example, while the Regulation may provide more flexibility by introducing new exceptions to the general requirement to obtain consent before processing health data (similar to what exists today in French law), the Regulation does not provide an exception for research. More troubling, recent versions of the Regulation leave the door open to Member State interpretation and legislating in the field of health, meaning that some countries may limit the use of patient data while others expand that use. In other words, the current situation - where national data protection laws based on the Directive's principles may sit aside national laws on health care that impact the collection and use of health and/or patient data - does not look likely to change under the Regulation.

This is a lost opportunity to build harmonization across the EU Member States. The fragmented approach to health and patient data processing that exists today in the EU contributes to “silo-ing” health data projects, particularly big data projects that rely on diverse information sources. For example, what may be permitted use of historical clinical data in one country may be prohibited in another country as unlawful “further processing” that is incompatible with the original purposes of data collection, and require in a third country specific licensing of the processing, all of which potentially reduces the scope of information on which researchers may base their studies.

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The benefits to be reaped from extending healthcare data usage are immense, as the multitude of use cases – of which only a few are highlighted in the present document – show. Going forward, healthcare stakeholders need to move beyond being obsessed with risks, and focus on capturing these benefits at measured risks.

More work will be required to design effective and operational solutions across and beyond the 4 areas for action outlined above. The potential impact on improving both quality and financial sustainability of health systems is well worth it.



ABOUT THE HEALTHCARE DATA INSTITUTE

The Healthcare Data Institute was launched in partnership with several companies representative of the Big Data health ecosystem. Its Board of Directors gathers representatives from Aviesan, CEA, IMS Health, McKinsey&Company, Medbiomix, Orange Healthcare, Sanofi, Vitalia.

The Healthcare Data Institute is acting as a forward-thinking catalyst in France and internationally.

It aims to develop thought leadership on Big Data for healthcare, be a catalyst for ideas, and foster the emergence of concrete projects.




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