WHY THE NHS MUST EMBRACE REAL WORLD DATA

By Fouad Lawal
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SVMPHARMA LIMITED
WINCHFIELD LODGE
OLD POTBRIDGE RD
WINCHFIELD, HAMPSHIRE
RG7 8BT UK

www.svmpharma.com
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Executive Summary

The unprecedented operational and financial challenges facing the National Health Service (NHS) have been well documented and are hardly ever out of the news. The massive gap in NHS funding in recent years and pressure on services caused by an aging population with multiple long term conditions are just some of the more widely reported reasons for the crisis. Various thinktanks and policy makers have put forward solutions to help reduce the pressures on the NHS. Primary among these are the integration of health and social care, greater emphasis on disease prevention and the introduction of new models of care into the NHS structure. In this paper, we argue that in order to navigate the difficult balance between financial sustainability and optimal performance the NHS needs to be more proactive in the collection and analysis of Real World Data (RWD) and exploit the multiple opportunities for commissioning RWD analysis at a local and national level. The current status quo and potential benefits to the NHS of gathering this type of data are also explored.
Introduction
There is a broad consensus that in order for the NHS to continue to meet the objectives and values for which it was set up, it must change the way in which it functions as an organisation. A downturn in the UK economy over the last decade or so has resulted in reduced government funding for the NHS. This, coupled with increased demand on services by an aging population means that the NHS now operates under remarkable financial and operational pressure.

It is estimated that if the current trajectory of flat government funding and growth in demand is maintained, the NHS in England will experience a funding deficit of around £30 billion per year by 2020/21. The NHS itself acknowledges that it needs to come up with smarter ways of resolving the financial and productivity challenges it faces, by promoting intelligent use of research data.

What is Real World Data?
The concept of gathering Real World Data has largely evolved in recent years as a result of the increased interest by health technology assessment (HTA) agencies in data which demonstrates the value and effectiveness of healthcare interventions. Real World Data (RWD) collection encompasses anything outside traditional randomised controlled trials (RCTs) and goes beyond what is normally investigated during phase III clinical trials in the evaluation of normal clinical practice.

There is increasing acknowledgement that classical RCTs while crucial to determine the safety and efficacy of a medicine, are inadequate to evaluate effectiveness in a practical real-life setting. RWD may be sourced from patient databases and disease registries (e.g. Hospital Episodes Statistics dataset or Clinical Practice Research Datalink), patient and population surveys, patient reported outcome measures (PROMS), patient reported experience measures (PREMS), observational studies, clinical audits and service evaluations.

Does the NHS use RWD?
In the UK, the NHS is the predominant source of clinical and patient data and it is reasonable to expect that information contained within the data would be routinely used as a performance management tool within the organisation. However, this potential is yet to be realised because of an apparent lack of awareness of the concept and its value to decision making. At present, the principal source of hospital data in England is the Hospital Episodes Statistics (HES) dataset. It contains over 125 million records from hospital Accident and Emergency, in-patient and outpatient departments every year. Analysis of the HES dataset is useful to monitor quality and safety of clinical procedures across hospitals and predict trends in hospital activity, resource use and disease patterns.

Unfortunately, many clinicians, commissioners and managers remain largely unaware of the existence of HES or are apathetic to its usefulness as a strategic planning and clinical safety tool. These stakeholders are largely restricted to the Secondary Uses Service (SUS) dataset which provides relatively basic information on patients’ hospital procedures and has problems of poor quality and incomplete data. Clinicians frequently exhibit a distrust of the integrity of available data and can be suspicious of the motives behind data collection, questioning whether the process might be used as a cost-cutting exercise or an opportunity to exert more managerial influence over them. Many clinical audits frequently run in hospitals or the medicines audits carried out by CCG medicines management teams do not achieve enough clinician engagement from the outset and can often focus on a narrow...
cost-cutting objective. These audits present an excellent opportunity to gather useful data from patient records and managers should do more to engage clinicians and patients to develop broader outcomes-based objectives which focus on aligning patients, clinicians and managers’ needs. Analysed data can potentially reveal hitherto unseen opportunities to optimise resource use and capacity, drive efficiency and promote positive patient outcomes. This must be the driving force behind the initiation of such projects.

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And there are signs that real world evidence increasingly influences how the NHS makes decisions. The controversial off-label use of bevacizumab (Avastin) in place of ranibizumab (Lucentis) in the treatment of wet age-related macular degeneration (AMD) offers a case in point. Real life clinical practice has shown that both treatments lead to similar outcomes and many clinicians are willing to use the unlicensed but cheaper bevacizumab for treatment of wet AMD. The NHS must strive to routinely evaluate health interventions in this way to drive access to innovative treatments and optimise resource use. It is notable that health technology assessment bodies are also starting to acknowledge the importance of using RWD to evaluate the true value of health technologies.

The National Institute for Health and Care Excellence (NICE) has indicated its willingness to explore additional drug analysis designs other than traditional clinical trials to aid decision-making. It is, together with other stakeholders across Europe working to develop standardised methodology for incorporating RWD into the drug development and reimbursement process. Another significant observation about data that is currently available to stakeholders is that they are mainly retrospective, reporting what has already occurred (e.g. the number of patients that have had a fall or perhaps had a drug allergy), but not what is happening at present or what may happen in future. In order to maximise the opportunities that real life data presents, the NHS needs not only to collect and analyse data, but attempt to gain an insight into the future by using innovative predictive analytics tools. Predictive analysis involves the use of technology and statistical modelling methods to search through massive amounts of data and analysing these to predict individualised patient outcomes. This approach has the capability to provide solutions to a range of healthcare problems, from assessing individual patients’ risk of contracting disease and identifying the most suitable treatments to reducing readmission rates and predicting healthcare workforce requirements.

A newly established National Information Board (NIB) charged with defining information technology strategy for the health and care system recently set out a framework for the transformation of care quality and outcomes through data and technology. It plans to make patient records accessible online in real time and, enable data integration across various health and care pathways. In addition to these, the NIB would do well to actively embrace the concept of predictive analytics so as to tap into the opportunities it offers for transforming healthcare and reach out to partners both within and outside of the NHS to ensure that the organisation does not miss out on what many observers consider to be the next big revolution in healthcare.

What are the options for data collection in the NHS?

RWD evaluation has for the most part been driven by the life sciences industry primarily to demonstrate the real world value and effectiveness of health technologies to reimbursement authorities. Some of these projects have been undertaken under a joint working arrangement between industry and the NHS where both parties pool together skills and
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resources in order to achieve aligned and agreed objectives which are targeted to improve patient outcomes.

The Salford Lung Study which was a collaboration between the NHS, Manchester University and Glaxo SmithKline is lauded as a prime example of this kind of arrangement.19 While there exists vast opportunity for similar mutually beneficial alliances to be forged between the NHS and the life sciences industry this has yet to happen on a large scale. There are inadequate mechanisms to foster transparency and trust between the involved stakeholders (patients, clinicians, commissioners, regulators and the pharmaceutical industry) regarding the benefits of data collection and a lack of assurance that appropriate safeguards to protect personal data are in place.20 Better communication and transparency about the benefits of RWD together with the development of a robust governance process for the handling of health data mutually acceptable to all stakeholders, are some of the steps which commentators suggest are required to build trust.21

In contrast to joint working arrangements, the NHS could also explore the use of innovative RWD analysis to support commissioning decisions by working directly with expert consultancies in the field. Particularly in the area of specialised commissioning for cancer and rare diseases, commissioners can use intelligent data analysis to better understand disease treatment pathways and the impact of health interventions on healthcare resources and outcomes. Many hospital trusts already commission consulting firms to gather data on patient experience and satisfaction (e.g. the NHS Friends and Family Test22) and may derive further benefit from tapping into data analytics expertise within these consultancies. A major advantage of this option is the ability to conduct independent projects which are free from bias of interested parties (commissioners or industry).

Commissioners and clinicians may also choose to proactively collect “in-house” data to support local clinical and commissioning decision-making. The routine audits carried out in primary care and hospitals must start to move beyond narrow cost-saving goals and more towards collecting data to establish “what really works” in real life clinical practice. Regional stakeholders should take a cue from NHS England’s, “Commissioning through Evaluation” program which aims to gather real world data on innovative health treatments that are not routinely funded due to a lack of evidence.23 This is particularly relevant to those services and treatments that are accessed by a relatively small number of patients.

Clinical commissioning groups (CCGs), hospitals and regional therapeutic guidelines bodies should collaborate to develop local “commissioning hotspots” for these treatments. Real life outcomes data and information obtained from these hotspots may then be shared to support decision making across health economies in the same region. Commissioners in the North East of England used this approach to support a decision to fund an innovative treatment, Xiapex (a collagenase injection used in the treatment of Dupuytrens contracture).Clinical audit data demonstrated that Xiapex enhanced patient experience and cost-effectiveness, leading to a positive decision by the North East Treatment Advisory Group (NETAG).24 Xiapex has since been approved for use in Scotland and Wales and in some CCGs across England. More recently, doctors at the Chelsea and Westminster Hospital in London carried out a real world clinical practice audit of the effects of dapagliflozin, a new treatment for type 2 diabetes, and compared their results to those
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reported in clinical trials. The outcome of this work supported the trust’s decision to commission dapagliflozin and make it accessible to eligible patients even before the treatment was approved by NICE. In addition to improving patients’ access to innovative treatments, this approach can foster closer ties between stakeholders and positively impact service redesign and the development of mutually beneficial payment mechanisms. Whatever option is chosen must be overseen by a robust data governance protocol which ensures that the process maintains the integrity of individual patients’ privacy and confidentiality.

Conclusion
It is clear that there is huge potential for RWD to revolutionise healthcare delivery as we know it. The current NHS leadership has committed to promoting innovation and the use of RWD in its five year plan to transform care, and while they have been generally well received, these plans stand the risk of remaining just that, if the will and commitment to implement them does not trickle down to local grassroots NHS stakeholders. Overflowing accident and emergency departments, delayed hospital discharges and the use of health interventions with inconclusive treatment outcomes are just some of the real everyday issues facing the health service. To better understand these issues and help drive innovative solutions to solve them, local NHS managers must invest in RWD.

Data monitoring and analytics can, amongst other things, help hospitals cut down on administrative costs, enhance clinicians’ real time decision making capabilities, improve co-ordination across care pathways as well as enhance the patient experience. Public hesitation over the extension of healthcare data use (as observed with the current debate over care.data) must be matched with adequate information and re-assurance to the public about a transparent governance mechanism which safeguards patients’ privacy. Despite all of its problems, the NHS still ranks as one of the most efficient healthcare systems in the world. However, in order for it to remain so, and continue to be at the forefront of developing cutting edge solutions to healthcare challenges, it cannot afford to conduct business as usual. The adoption of a top-to-bottom culture of working with Real World Data offers a viable opportunity to achieve this.
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