Mayden

The power of data to transform care in psychological therapies

Chris May
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Mayden

Contents

Introduction

Big data. Machine learning. Artificial intelligence. Data science. Personalised healthcare. Digital.

These terms are increasingly heard around healthcare, but what do they mean? How do they differ from one another? And what do they have to do with psychological therapy?

Not too much, you would be forgiven for thinking! The interaction between two human beings that lies at the heart of psychological therapy requires skillful observation and interpretation. It relies upon the application of nuanced, specialist knowledge by the clinician in order to achieve desired patient outcomes.

Yet psychological therapy is, of course, evidence-based. That evidence is derived from the analysis of large amounts of patient data. Findings then influence treatment recommendations, and are even used to create standardised care protocols such as NICE guidelines. These two components of evidence-based care – data analysis and standardisation – work hand in hand: the more significant the analysis, the weightier the evidence indicating when to standardise care; the more standardised the care and data collection, the greater the opportunities for reliable analysis.

On both counts, the national psychological therapy programme in England, Improving Access to Psychological Therapies (IAPT) is perhaps already in the strongest position of any clinical specialty in the NHS, or any psychological therapy programme in the world. With NICE guidance, a nationally mandated dataset, and having treated millions of patients over its first decade, both IAPT's delivery of evidence-based care and its data collection are consistent, highly structured and plentiful. Crucially, when it comes to informing practice, IAPT also collects routine outcome measures for almost all patients treated through the programme.

So is IAPT making best use of this enviable position? Are we learning all we can from that wealth of high quality data, about how the best outcomes can be achieved for different types of patients? Is care being standardised wherever appropriate? Can that standardisation lead to even greater data insights?

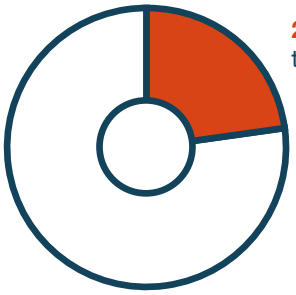
At Mayden, our purpose is to use data driven technologies to change what is possible for clinicians and patients. In this paper, we introduce SAPIO – a project which aims to explore how data analytics and the standardisation of care can be used to improve outcomes for patients at scale.

Working as a technology partner alongside clinicians, we seek to streamline and standardise the assessment-to-treatment pathway, and to build technologies that can support clinicians in their clinical decision making.

Context and need

Mental health issues account for 23% of NHS activity, and cost the UK economy an estimated £105 billion a year. Every week, 1 in 6 adults experiences a common mental health problem that would benefit from psychological therapy, such as anxiety or depression.

Launched in 2008 to transform the treatment of adult anxiety disorders and depression in England, the IAPT programme is already a colossus in healthcare. It sees around 1 million patients per year, and is set to double in size by 2024 under the NHS Long Term Plan (LTP)[01]. The LTP also sets out plans to treat 345,000 more 0-25 year olds by 2023/24.



23% of NHS activity is related to mental health issues

IAPT in numbers

140 adult IAPT services across England

Approximately **7,000 therapists**

1.6 million referrals in 2018/19

1.1 million referrals started treatment

Nearly **90%** of these started treatment within 6 weeks (target 75%) and nearly all within 18 weeks (target 95%)

Just under **600,000** completed treatment

Average **6.9 sessions**;
7.6 sessions for those who achieved recovery

52% moved into recovery (target 50%)

67% achieved reliable improvement (target two thirds)[02]

All this by increasing access levels whilst maintaining waiting times and recovery rates within the programme. At present, access rates stand at just under 20% of prevalence and are expected under the LTP to escalate to 25%. National wait time targets for starting treatment are being met (see **IAPT in numbers**, above), but there is concern about wait times after the initial appointment has been delivered[03].

01 NHS. (2019). The NHS Long Term Plan. [Online]. Available at: https://www.longtermplan.nhs.uk/publication/nhs-long-term-plan/ [Accessed 11 September, 2019].

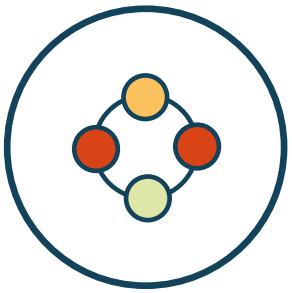
02 NHS Digital. (2019). Talking therapies: New statistics show an increase in referrals, numbers starting treatment and recovery rates during 2018-19. [Online] Available at: https://digital.nhs.uk/news-and-events/latest-news/iapt-2018-19 [Accessed 16 September 2019].

03 Gregory, A. (2019). More than 120,000 NHS patients kept on 'hidden waiting lists' for mental health appointments. Independent. [Online] Available at: https://www.independent.co.uk/news/health/nhs-mental-health-treatment-therapy-waiting-list-appointment-a9079541.html [Accessed 16 Sep. 2019].

The national recovery target of 50% only began to be achieved in the last two years, and currently stands a little over that. However, this relates to patients who completed a course of treatment; around half of patients who begin treatment do not continue to engage to the end of a treatment course[04].

All in all, the anticipated LTP expansion can only come with a transformation in how care is delivered – particularly if engagement and outcomes are also to improve for the benefit of patients. The LTP anticipates this challenge, specifying the key role of digital technologies alongside an expansion of the workforce. By 2021/22 digitally-enabled therapy models will be rolled out for specific mental health pathways. Two years later, local systems will offer a range of self-management apps, digital consultations and digital clinical decision-making tools supporting detection of need, assessment and treatment.

The IAPT Manual[05] identifies that a key feature of a high performing IAPT service is a focus on innovation, research and the digital agenda. Many mental health services have already integrated digital modalities into their care pathways. Through a previous development project, Mayden was able to help services leverage uptake of online therapies by making referral and monitoring far easier for IAPT services. The **Prism** online therapy referral hub integrated within our Electronic Patient Record (EPR), **iaptus®**, currently routes around 70,000 referrals from 57 IAPT services to digital treatment each year.



But is this digital transformation going far enough and fast enough to support clinicians in improving access, engagement and outcomes for their patients on a scale that is needed?

Signalling intent to accelerate the adoption of even more advanced technologies, the NHS has recently announced the opening of a new artificial intelligence laboratory to “help solve some of healthcare’s toughest challenges”[06]. Further, a recent report by the Reform think tank into data-driven technologies in mental healthcare identified two key areas – first streamlined triage and assessment, and second data-driven clinical decision support – where advanced technologies could deliver key benefits to services[07].

04 Psychological Therapies, Annual report on the use of IAPT services 2018-19. (2019). [online] NHS Digital. Available at: https://digital.nhs.uk/data-and-information/publications/statistical/psychological-therapies-annual-reports-on-the-use-of-iapt-services/annual-report-2018-19 [Accessed 16 Sep. 2019].

05 NHS England. (2019). The Improving Access to Psychological Therapies Manual. [Online]. Available at: https://www.england.nhs.uk/publication/the-improving-access-to-psychological-therapies-manual/ [Accessed 11 September, 2019].

06 Introducing NHSX’s new national artificial intelligence laboratory. (2019). [Blog] Technology in the NHS. Available at: https://healthtech.blog.gov.uk/2019/08/08/introducing-nhsxs-new-national-artificial-intelligence-laboratory/ [Accessed 11 Sep. 2019].

07 Reform (2019). Making the right choices Using data-driven technology to transform mental healthcare. [online] London. Available at: https://reform.uk/research/making-right-choices-using-data-driven-technology-transform-mental-healthcare [Accessed 11 Sep. 2019].

These two areas identified for digital transformation correspond, perhaps unsurprisingly, with the two key drivers of evidence-based care identified above – standardisation and data analysis. These are also two of the six emerging themes from a recent national conversation we at Mayden have had with clinical and service leads, CIOs and CCIOs about the future of healthcare delivery (see below).

A vision for the future of mental healthcare

At Mayden, our life's work is creating digital technology that changes what's possible for clinicians and patients. We design, build and support insightful IT systems for healthcare in the UK and abroad.

In 2018 we toured the country asking clinical service leads, CIOs and CCIOs in a number of mental health trusts what they thought was on the horizon for healthcare and IT.

Six themes emerged:

1. Standardised care pathways and treatment protocols
2. Decision support tools
3. 'Patient first' (enabling patients to be engaged in their care, notes and data)
4. Much wider adoption of routine outcome measurement
5. Improved user interfaces and experience of using healthcare IT systems
6. System interoperability

Mayden is building its future roadmap around these themes. The SAPIO project focuses on the first two in particular, though addresses all six themes to some extent.

Let's take a look at these two areas – streamlined and standardised assessment, and data-driven decision support – and available technologies, before turning to the SAPIO project, which aims to test their potential in IAPT in collaboration with clinicians.

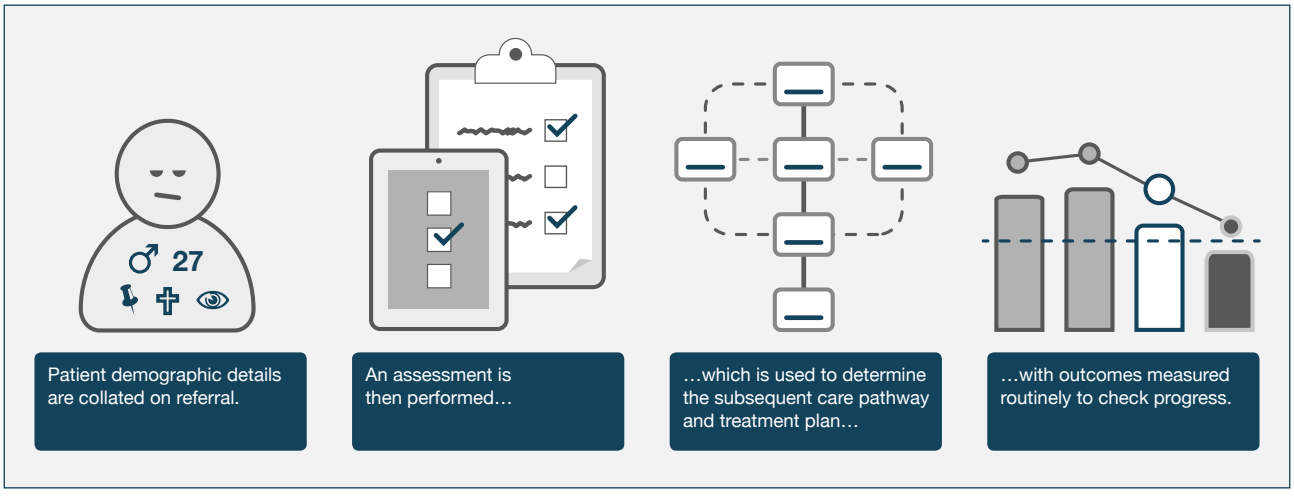
Streamlined and standardised assessment

Assessment is the first thing that happens when a patient is referred and before treatment can commence.

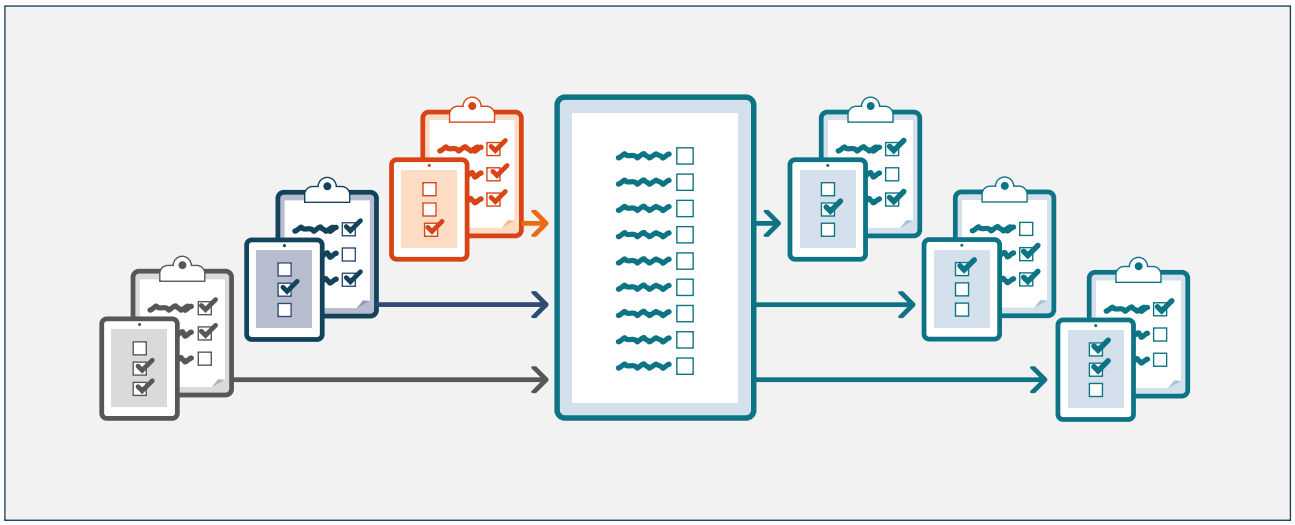
This covers triage to check the patient's suitability for the service, as well as the clinical assessment leading to diagnosis and decisions about treatment. The IAPT Manual[08] recommends that patient assessments should include systematic screening for a range of conditions using standardised screening questionnaires that are completed by the patient before they attend.

Despite its strong national delivery framework, IAPT does not have a standardised assessment process to achieve this. The process varies by service, with patients being asked a range of questions at different stages via forms of varying length, or during appointments, with a number of different types of staff. Furthermore, services report that a

> The assessment plays a pivotal role in helping clinicians to direct a patient towards treatment pathways most likely to have a beneficial outcome.



08 NHS England. (2019). The Improving Access to Psychological Therapies Manual. [Online]. Available at: https://www.england.nhs.uk/publication/the-improving-access-to-psychological-therapies-manual/ [Accessed 11 September, 2019].



Combining existing disparate assessments into a standardised framework paves the way for the application of data technologies.

significant amount of time is spent signposting patients found to be unsuitable for IAPT to other services. Interviewees for the recent Reform report noted that "forms can be 'astonishingly long' and off-putting for patients"[09]. The authors identified various data-driven tools already under development to improve patients' and clinicians' experiences of triage, and reduce the length of time it takes, including the use of conversational chatbots programmed to replicate NICE guidelines as an alternative to completing forms[10].

Standardising and streamlining assessment would make better use of clinician time, improve patient experience, and reduce wait times before treatment – and eventual improvement and recovery – can start. If the assessment is also consistently structured so that one patient's profile can be compared to the profiles of previous patients with similar profiles, then it might be possible to generate treatment insights based on the experience and outcomes of those past patients. This, alongside NICE guidance and the clinician's own knowledge base, could assist the clinician in their treatment decisions – with the prospect of even greater and/or faster recovery.

Let's now look at the latest data analytic tools that might make this possible.

09 Reform (2019). Making the right choices Using data-driven technology to transform mental healthcare. [online] London. P.3. Available at: https://reform.uk/research/making-right-choices-using-data-driven-technology-transform-mental-healthcare [Accessed 11 Sep. 2019].

10 Reform (2019). Making the right choices Using data-driven technology to transform mental healthcare. [online] London. P.23. Available at: https://reform.uk/research/making-right-choices-using-data-driven-technology-transform-mental-healthcare [Accessed 11 Sep. 2019].

Advanced data analytics and decision support

> "Advances in machine learning and artificial intelligence (AI) offer the potential to provide personalised care that is equal to or better than the performance of humans for several health-care tasks." [11]
>
> **Ghassemi, M. et al. (2019) Practical guidance on artificial intelligence for health-care data**

Every IAPT service collects and submits significant amounts of highly structured, consistent and complete data, including patient assessments and outcome measures.

Some services simply collect and submit their data for reporting against the national dataset. Others use their own data to varying degrees to understand what is working in their service and what could be improved. With appropriate permissions, subsets of locally or nationally aggregated data could be used for research purposes, to grow our knowledge of effective treatment and service delivery[12].

In this digital age, vast quantities of data of many kinds are generated each day. This, along with advances in computer processing power and lower cost of secure data storage, has sparked the field of 'big data' analytics over the last two decades.

11 Ghassemi, M. et al. (2019) 'Practical guidance on artificial intelligence for health-care data', The Lancet Digital Health, [Online]. 1, 4. Available at: https://www.thelancet.com/journals/landig/article/PIIS2589-7500(19)30084-6/fulltext [Accessed 11 September 2019].

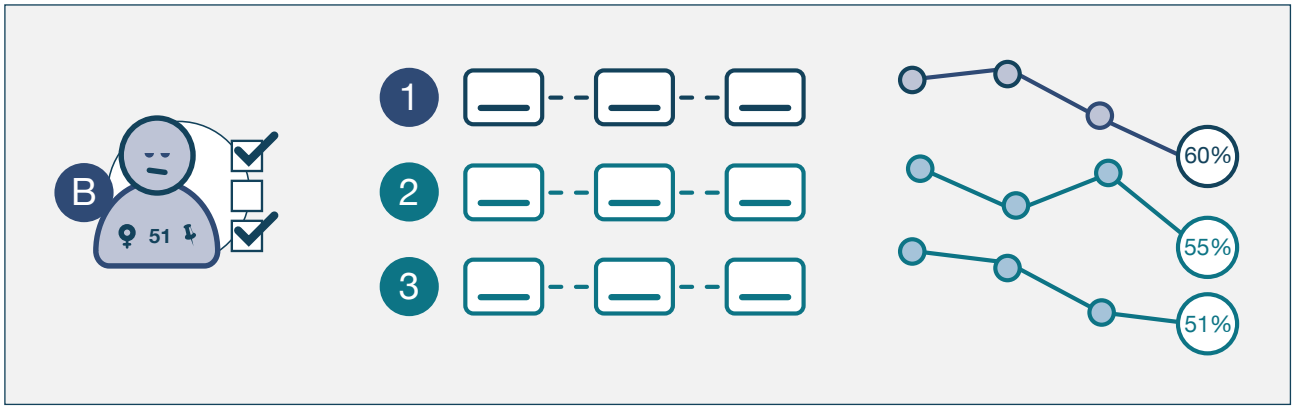
12 Clark, D., Canvin, L., Green, J., Layard, R., Pilling, S. and Janecka, M. (2017). Transparency about the outcomes of mental health services (IAPT approach): an analysis of public data. The Lancet, [online] 391(10121). Available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)32133-5/fulltext [Accessed 16 Sep. 2019].

Machine learning (ML) is a form of artificial intelligence (AI)[13]. Machine learning tools are able to take massive datasets and find patterns and relationships between data points within them – for example, between input data and outcome measurements. Having been trained on historical datasets, the machine learning model can be applied to current datasets to predict outcomes and therefore provide clinicians with insights that support their decision making[14].

Machine learning could be applied to the millions of existing IAPT patient records, finding patterns between patient assessments, diagnosis, the treatment they received and their outcomes, and could then generate a model that reproduces those patterns. That model could then be applied to any new patient assessment in order to suggest the treatment that is most likely to achieve the best recovery, based on historical patients with similar profiles.

Shatte et al recently reviewed the existing research literature for studies where ML had been applied to mental health conditions[15]. They found that to date, studies have mainly focused on detection and diagnosis (eg suicide prevention), but that there is growing interest in using ML to inform treatment decisions. One study found that whilst traditional statistical methods were unable to predict outcomes from internet-delivered CBT in children with OCD, four different ML-generated algorithms achieved predictions with 75-83% accuracy[16]. Clinical decision support tools are also beginning to use newer techniques

Using millions of historic records, ML can predict the chances of recovery for different treatment pathways for each individual patient.



13 Big data, artificial intelligence, machine learning and data protection. (2019). Data Protection Act and General Data Protection Regulation. [online] Information Commissioner's Office, p.7. Available at: https://ico.org.uk/media/for-organisations/documents/2013559/big-data-ai-ml-and-data-protection.pdf [Accessed 16 Sep. 2019].

14 Shatte ABR, Hutchinson DM, Teague SJ. (2019). Machine learning in mental health: a scoping review of methods and applications. Psychological Medicine 49, 1426–1448. https://doi.org/10.1017/S0033291719000151

15 Shatte ABR, Hutchinson DM, Teague SJ. (2019). Machine learning in mental health: a scoping review of methods and applications. Psychological Medicine 49, 1426–1448. https://doi.org/10.1017/ S0033291719000151

16 Lenhard, F., Sauer, S., Andersson, E., Månsson, K., Mataix-Cols, D., Rück, C. and Serlachius, E. (2017). Prediction of outcome in internet-delivered cognitive behaviour therapy for paediatric obsessive-compulsive disorder: A machine learning approach. [online] 27(1). Available at: https://onlinelibrary.wiley.com/doi/abs/10.1002/mpr.1576 [Accessed 16 Sep. 2019].

like ML so they can draw on even larger and more complete patient datasets to improve their accuracy[17].

Machine learning, as described, is a paradigm shift from the Randomised Control Trial (RCT) for deriving knowledge about the effect of different treatments on different patients. RCTs, considered the gold standard for scientific knowledge, enable variables to be controlled to understand causal relationships at group or population level. But RCTs can be lengthy and expensive. They are not always practical to carry out, and can only examine a very limited number of variables at once under laboratory – rather than real world – conditions. They can also present significant ethical dilemmas when managing interventions across control and experimental groups.

Machine learning on the other hand can handle multiple variables within mixed, unstructured and incomplete data from real world settings, in order to identify patterns and relationships that shed light on the effectiveness of a particular treatment at the level of the individual rather than group. However, the sheer complexity of the mathematical modelling can result in a 'black box' effect where it may not always be possible for data scientists or clinicians to understand how the model arrived at a particular conclusion. Whilst RCTs interrogate the data with discrete, narrow questions, ML lets the datasets "speak for themselves"[18].

Experts are drawing the conclusion that ML and RCT should both be used, having the potential to work together with the existing knowledge base to inform clinical decisions about treatment. The study of children with OCD cited previously was an RCT that employed ML analytical tools on the collected data over traditional statistical analysis techniques[19] [20]. The combination of ML and RCTs with traditional statistical techniques will blur the lines between laboratory and real world settings, and enable greater personalisation of evidence-based treatment recommendations.

iaptus EPR in numbers

Used by **130 adult IAPT** and **41 Children & Young People's (CYP)** services

5 million patient records created to date

1.2 million referrals handled in last 12 months

5.8 million sessions last year

Handled nearly **290,00 online self-referrals** in last 12 months

17 Reform (2019). Making the right choices Using data-driven technology to transform mental healthcare. [online] London. P.17. Available at: https://reform.uk/research/making-right-choices-using-data-driven-technology-transform-mental-healthcare [Accessed 11 Sep. 2019].

18 Bzdok, D. and Meyer-Lindenberg, A. (2019). Machine Learning for Precision Psychiatry: Opportunities and Challenges. Biological Psychiatry. [online] Available at: https://www.biologicalpsychiatrycnni.org/article/S2451-9022(17)30206-9/fulltext [Accessed 17 Sep. 2019].

19 Lenhard, F., Sauer, S., Andersson, E., Månsson, K., Mataix-Cols, D., Rück, C. and Serlachius, E. (2017). Prediction of outcome in internet-delivered cognitive behaviour therapy for paediatric obsessive-compulsive disorder: A machine learning approach. [online] 27(1). Available at: https://onlinelibrary.wiley.com/doi/abs/10.1002/mpr.1576 [Accessed 16 Sep. 2019].

20 Dipnall, J., Pasco, J., Berk, M., Williams, L., Dodd, S., Jacka, F. and Meyer, D. (2016). Fusing Data Mining, Machine Learning and Traditional Statistics to Detect Biomarkers Associated with Depression. PLOS ONE. [online] Available at: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0148195 [Accessed 16 Sep. 2019].

Shatte et al concludes:

> "It is evident that there is significant room for the application of ML to other areas of psychology and mental health […] Overall, ML demonstrates the potential to improve the efficiency of clinical and research processes and to generate new insights into mental health and wellbeing […] Such analytic techniques are also being explored with mental health data, with the broad potential of both improving patient outcomes and enhancing understanding of psychological conditions and their management."
>
> **Shatte et al**

However, they also found "very little research […] that demonstrated the use of ML techniques in real-world settings, suggesting that further research is required to test clinical utility."

To that end, Longhurst et al put forward a vision five years ago of a "green button" function within an electronic health record which a clinician can click to generate treatment insights at the point of care from aggregated data across stored patient records[21].

Could this actually become a reality now? Could psychological therapy services, in partnership with Mayden, pioneer such an innovation within the iaptus health record to achieve the clinical utility that Shatte et al describe?

The **SAPIO project**, which we turn to next, aims to find out.

21 Longhurst, C., Harrington, R. and Shah, N. (2014). A 'Green Button' For Using Aggregate Patient Data At The Point Of Care. Health Affairs, [online] 33(7). Available at: https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0099 [Accessed 16 Sep. 2019].

The SAPIO project

Mayden has been awarded Small Business Research Initiative (SBRI) Healthcare funding to undertake the SAPIO project.

SAPIO is an acronym for **S**treamlining **A**ssessment **P**athways, **I**mproving **O**utcomes, which expresses the overall purpose and vision of the project. SAPIO will support the digital transformation of the referral to treatment pathway.

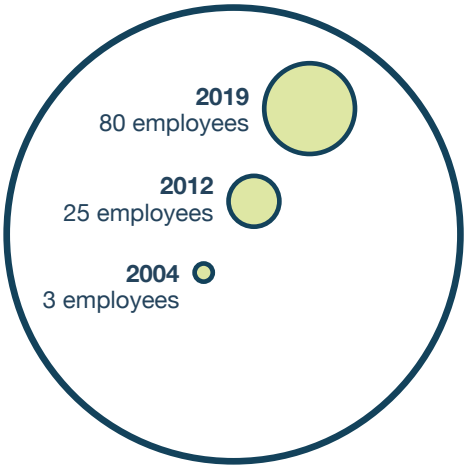
About SBRI Healthcare

SBRI (Small Business Research Initiative) Healthcare is an NHS England funded programme that provides funding and support to innovative companies to solve healthcare problems. The SBRI Healthcare team works closely with clinicians and frontline NHS staff to identify key challenges from within the service, focussing on specific areas recognised as priority by NHS England and the 15 Academic Health Science Networks (AHSN). The programme aims to improve patient care, increase efficiency in the NHS, and support the UK economy by helping smaller companies grow.

Since launching in 2009, £90 million has been awarded to over 200 companies developing solutions for major NHS challenges such as cancer detection, dementia care, mental health and self-management of long-term conditions. The programme currently has over 50 companies under contract with over 2000 applications received, and a pipeline independently evaluated to deliver cumulative cost savings to the NHS of £350M to £480M by 2022.

About Mayden

Mayden is the company behind iaptus, the market leading psychological therapy patient management system which is trusted by 70% of England's Improving Access to Psychological Therapies (IAPT) services. Established 15 years ago, Mayden has grown by 15% a year and now has 130+ NHS, private and third sector healthcare providers as clients and turns over more than £5m a year.



The project's main aims are to:

Streamline and digitise each stage of the patient journey from the point of referral – through assessment and appointment booking – to the start of treatment.

Leverage historical IAPT patient data at key decision points in the pathway for insights about how individual patients will best engage and respond to treatment.

Use greater standardisation through the assessment stage, along with IAPT's excellent data collection around diagnosis, treatment and outcomes, to improve the opportunity for even more reliable treatment insights into the future.

Key objectives of SAPIO

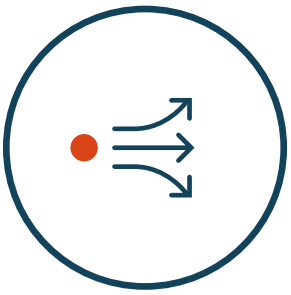
1. Standardised initial patient assessment
2. Digitisation of standard assessment so patients can self-complete
3. Smart appointment booking by patients, based on treatment pathways
4. Machine learning to:
   - digitise triage regarding suitability for the service
   - generate treatment insights from previous patients with similar profiles that may support clinician decision making with current patients
   - identify patients at risk of failing to engage
5. Investigate the possibility and potential benefits of matching behavioural preference profiles of clinician and patient
6. Explore the application of the above concepts for CYP services

An initial phase of the project completed last year with SBRI's support tested the technical feasibility of SAPIO in collaboration with clinical services. Together we found that:

- The concept of a standardised assessment received national interest and wide support from clinicians. We found wide variations in assessments across services as well as some reservations amongst clinicians about whether standardised assessment is practically achievable. However, we also found a high level of support for improving the assessment process.
- A prototype digital assessment was adopted into daily use by a large IAPT service, demonstrating that patients are willing to self-assess online. Up to 800 patients per month used it during the trial. However, we found that clinician-patient contact needs supporting at crucial points in the digital assessment workflow to avoid disengagement.
- A prototype machine learning algorithm was successfully developed which generated sensible predictions and treatment insights. The algorithm was able to predict whether or not a patient will recover from a given treatment type with precision[22] greater than 90% and accuracy[23] of 68.90% (+/- 0.83%). This has the potential to increase recovery rates by 12.5% (from 50% to 62.5%), and, for patients who did recover, to improve outcomes by a further 5%.

The new funding award is intended to expand on this technical feasibility work, including:

- Gaining wider engagement and collaboration from the clinical community in exploring new technologies like machine learning in practice.
- Developing with clinicians a standardised assessment, then digitising this and the rest of the referral to treatment pathway.
- Improving the accuracy of machine learning generated insights developed in phase one of the project.



22 Machine Learning. (2019). Classification: Precision and Recall. [online] Available at: https://developers.google.com/machine-learning/crash-course/classification/precision-and-recall [Accessed 16 Sep. 2019].

23 Machine Learning. (2019). Classification: Accuracy. [online] Available at: https://developers.google.com/machine-learning/crash-course/classification/accuracy [Accessed 16 Sep. 2019].

Benefits

SAPIO has the potential to deliver:

- **Improved outcomes** and **faster recovery**
- **Clinician decision support** through targeted treatment insights
- **Shorter waits** between referral and subsequent stages in the assessment and treatment pathway
- **Streamlined workflow**
- Patients not appropriate for IAPT **screened out sooner and signposted to alternative support**
- **Improved patient engagement**
- Patients given the ability to **book their own appointments**, tailored appropriately
- **Regular updates to the patient** on their progress through the care pathway

The following sorts of **cost savings**, which have been independently reviewed by an SBRI health economist, may be realised by the NHS from innovations within SAPIO:

Digitising the assessment process for over 1m patients could release more than £50m in cost savings to the NHS.

Machine learning could identify groups that may benefit from digital interventions earlier, with estimated savings from increased adoption of digital therapy of £27m, but greater savings could be achieved with full digital capacity.

The ML algorithm should be able to identify patients who would recover with less than six sessions without compromising outcomes, leading to potential savings of £1.5m.

Responsible data-driven technology

> "Mental health presents tensions and 'sensitivities' that create specific challenges for the application of data-driven technologies. Approaches to diagnosis and treatment must be nuanced and contextualised. People living with mental illness face discrimination and stigma, creating barriers to accessing high-quality care, as well as heightened concerns about how patient data is accessed." [24]
>
> **Reform (2019)**

Whilst advanced data analytic techniques may have the potential to revolutionise how we acquire and use insights about the effectiveness of care in the clinical setting, good governance of patient care and patient data remain of paramount importance. The two must be managed appropriately.

Data reporting, analytics and visualisation are common activities for any services. The creation, curation, adaptation and maintenance of the data analytics features within products like iaptus are covered by service level agreements between data controller (service) and data processor (system supplier eg Mayden), and data protection laws.

An ML project processes large quantities of patient data to derive insights from it. The Information Commissioner's Office (ICO) recognises that big data activities such as machine learning present particular challenges for data protection and privacy. Existing regulatory frameworks have developed in the context of conventional data processing paradigms. In this context, the ICO has highlighted the

24 Reform (2019). Making the right choices Using data-driven technology to transform mental healthcare. [online] London. P.2. Available at: https://reform.uk/research/making-right-choices-using-data-driven-technology-transform-mental-healthcare [Accessed 11 Sep. 2019].

overarching importance of transparency, fairness and accountability for how data is used with these advanced techniques.

The ICO also stresses that data protection is not necessarily a barrier to ML: "Embedding privacy and data protection into big data analytics enables not only societal benefits […] but also organisational benefits like creativity, innovation and trust. In short, it enables big data to do all the good things it can do." Using anonymised patient data only, for example, is one key step that can be taken with regard to GDPR regulations[25].

Equality and fairness are key values and obligations of the NHS. Bias and lack of transparency leading to discrimination are common criticisms of big data technologies including ML[26]. Whilst human decision makers can of course be influenced by conscious and unconscious bias, it is incumbent on data science that historical biases introduced by humans are not perpetuated, nor new ones introduced. This is especially true given that today's decisions based on historical insights can affect the data used to train future models, meaning that any biases in today's data can become embedded in future models. ML projects can mitigate the risk of introducing bias through careful validation at every stage of the project by practitioners: first, through expert practitioner validation of the research themes that are chosen and a validation of the planning of the research; second through a careful analysis of the results using standard, tried and tested statistical methods used for eliminating bias; and finally through expert, clinical validation of the working prototypes and product.

There is then the consideration of whether ML-driven decision support applications are classed – and should be regulated – as medical devices. This does not stop them from being developed during the project phase, but determines when they might be used in a live clinical environment.

Finally, research and development projects involving new data technologies raise their own ethical considerations. Some have suggested that the potential influence of ML in healthcare means

Data Security at Mayden

We know that our success stands and falls on our good governance of patient data. To that end, Mayden has been accredited to the ISO 27001 Information Security Management standard since 2015, and complies with the NHS Data Security Protection Toolkit (previously IG Toolkit). We manage clinical safety to conform with the NHS pioneering standard DCB 0129 for software development.

25 Big data, artificial intelligence, machine learning and data protection. (2019). Data Protection Act and General Data Protection Regulation. [online] Information Commissioner's Office, p.3. Available at: https://ico.org.uk/media/for-organisations/documents/2013559/big-data-ai-ml-and-data-protection.pdf [Accessed 16 Sep. 2019].

26 Dastin, J. (2018). Amazon scraps secret AI recruiting tool that showed bias against women. Reuters. [online] Available at: https://www.reuters.com/article/us-amazon-com-jobs-automation-insight/amazon-scraps-secret-ai-recruiting-tool-that-showed-bias-against-women-idUSKCN1MK08G [Accessed 16 Sep. 2019].

that data scientists should be required to subscribe to a code of conduct similar to the Hippocratic oath[27].

In July 2019, the NHS published a Code of Conduct for data driven technologies in healthcare, addressing the issues highlighted above. Other codes and guidelines are similarly recent (see below). It is clear that the regulatory framework around these technologies is emerging at the same time as the application of the technologies themselves. Mayden will work closely with NHS partners throughout the SAPIO project to navigate, and act appropriately within available guidelines for data usage.

Regulation, guidance and good practice

A regulatory and advisory framework for data driven technologies is fast emerging to keep pace with innovations. Relevant codes include:

- *Code of Conduct for data driven technologies in health and care*. Dept of Health and Social Care (July 2019)[28]
- Data Protection Act 2018 (GDPR)[29]
- Department for Health and Social Care *Code of conduct for data-driven health and care technology* (July 2019)[30]
- MHRA Medical devices: *software applications guidance* (last updated June 2018)[31]
- National Institute For Health And Care Excellence *Evidence Standards Framework For Digital Health Technologies* (December 2018)32

The dates of publication of a number of these demonstrate that we are in an era where the regulatory and legal framework is developing at the same time as the healthcare applications themselves. Updates, interpretation, practical application and precedents will need to be kept under continuous review.

27 Guardian (2019). Maths and tech specialists need Hippocratic oath, says academic. [online] Available at: https://www.theguardian.com/science/2019/aug/16/mathematicians-need-doctor-style-hippocratic-oath-says-academic-hannah-fry?CMP=Share_iOSApp_Other [Accessed 17 Sep. 2019].

28 Code of conduct for data-driven health and care technology. (2018). Guidance. [online] Department of Health and Social Care. Available at: https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology [Accessed 16 Sep. 2019].

29 Data Protection Act 2018. (2018). UK Public General Acts. [online] Available at: http://www.legislation.gov.uk/ukpga/2018/12/contents/enacted [Accessed 30 Sep. 2019].

30 Code of conduct for data-driven health and care technology. (2018). [online] Department of Health and Social Care. Available at: https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology [Accessed 30 Sep. 2019].

31 Medical devices: software applications (apps). (2014). [online] Medicines and Healthcare products Regulatory Agency. Available at: https://www.gov.uk/government/publications/medical-devices-software-applications-apps [Accessed 30 Sep. 2019].

32 Evidence standards framework for digital health technologies. (2018). [online] NICE. Available at: https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/digital-evidence-standards-framework.pdf [Accessed 30 Sep. 2019].

Working together

> "We recommend that clinicians and AI researchers work collaboratively to pair clinical challenges with novel technical solutions. Engaging in close partnerships will create meaningful algorithms, foster community, and form culture." [33]
>
> **Ghassemi, M. et al.**

At Mayden, one of our four abiding values is collaboration.

We develop new technologies using Agile methodologies which put the user at the centre of decision making and progress. We frequently co-create solutions with our clients. After all, that is how iaptus was developed in the first place – in collaboration with one of the very first IAPT pilot sites.

We seek to work with IAPT services throughout the SAPIO project, and are looking for clinicians to join us as we develop and test the potential of the various features within SAPIO. This might include:

- Sharing your service's assessment protocol and collaborating with others over the content of a single standardised assessment, then testing it.
- Providing user feedback as we develop smart appointment booking to connect with the diary in iaptus.
- Contributing anonymised patient data to the project for testing the feasibility of treatment insights in clinical decision making.
- Evaluating treatment insights generated by machine learning algorithms.
- Piloting new features within your service.

33 Ghassemi, M. et al. (2019) 'Practical guidance on artificial intelligence for health-care data', The Lancet Digital Health, [Online]. 1, 4. Available at: https://www.sciencedirect.com/science/article/pii/S2589750019300846?via%3Dihub [Accessed 11 September 2019].

Conclusion

Big data. Machine learning. Artificial intelligence. Data science. Personalised healthcare. Digital. These are the emerging technologies that are set to transform the healthcare landscape over the coming years.

The NHS Long Term Plan has signalled that digital transformation will be key to meeting its objectives, and senior NHS leaders at both national and trust level have demonstrated their intent to embrace a digital first strategy. These technologies are here to stay.

At Mayden, using digital to change what's possible for clinicians and patients is our life's work and, with iaptus and Prism, we feel deeply privileged to have played our part in an emerging mental health model that is admired around the world.

IAPT services are in a relatively unique situation. With millions of patient contacts at which outcome measurements have been recorded, IAPT services occupy an enviable position – not just in the NHS but on the global stage – in which the potential benefits of these new digital tools can be realised. We believe the data in the IAPT dataset can inform and enhance the interaction between therapist and patient resulting in faster treatment, more choice, improved outcomes, and significant cost savings.

These benefits will be hard won. We will need to work together to achieve them. In the world of digital, the more we standardise the data, the more we can personalise the treatment. So streamlining the assessment process across services will be critical. Machine learning has the power to significantly transform clinical decision-making but we need to recognise that this will take time. It is not only the machines thatneed to learn. We need to accept and embrace the data protection, privacy, ethics and clinical safety challenges that will inevitably present themselves as we move forward.

The prize is worth the effort. All these obstacles can be overcome, but only if we collaborate. Many of the IAPT services we support have already expressed interest in being involved in the SAPIO project.

If you would like to join them and participate in any of the ways described, please contact Philippa Kindon at projects@mayden.co.uk

Chris May is the Founding Director of Mayden. Formerly from a manufacturing background, he has dedicated the last 27 years of his career to the healthcare sector. He is passionate about maximising the opportunities presented by technology both to provide joined up healthcare and to increase the cost-effectiveness of healthcare IT.

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The Old Dairy, Melcombe Road, Bath BA2 3LR
T: 01249 701100
mayden.co.uk

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