Finding the Right Patients for Primary Care Clinical Studies

Automated Recruitment Platforms (ARPs) offer primary care clinicians and allied health professionals' opportunities for more time-efficient ways to engage with and recruit patients for clinical studies. This is compared to traditional 'manual' methods such as phone and paper-based approaches. Dr. Matt Wilson, who founded clinical research platform uMed, outlines the benefits of the technology and explains why the patient Electronic Health Record (EHR) alone, although essential, is not a sufficient data set for successful clinical study recruitment in primary care. Automated patient recruitment can benefit healthcare providers and their patients by helping to recruit the right patients with targeted studies more promptly, at greater scale and with less impact on practice workload in a data-secure way.

What Automated Recruitment Platforms (ARPs) do

Automated Recruitment Platforms are a relatively new health technology solution which use smart phone, text/SMS, social media and other electronic communications to engage with a patient in a more individualised, data-secure way than traditional manual approaches when recruiting patients for clinical studies. They are able to shorten, safely, the time span needed for a clinical study and, with a patient's consent, combine their EHR with other data sources such as the patient's digital engagement with a health provider over time. This enables a health provider, for example a local community health centre, to match eligible patients to appropriate clinical studies, providing more accurate and richer data for the clinical study sponsor.

The challenges for patient recruitment in primary care

A major challenge for delivering research in primary care settings is the limited capacity for healthcare providers to support the extensive logistics needed for clinical studies. It requires time, knowledge of the research process, and often capital expenditure to set up the infrastructure to deliver research programmes. Secondary care health services, for example clinicians in hospital settings, often have more infrastructure, capacity and experience in undertaking clinical studies, including randomised controlled trials. In primary care, the time invested in a clinical study equates to precious time and budget expended away from clinical demands. Primary healthcare professionals, for example GPs in the UK, family physicians, practice nurses and allied health professionals, often find it difficult to accommodate this time, given their operational model and more urgent clinical responsibilities. The result is that opportunities for clinical research in primary care are lost as potential study sites decide against involvement. Even when a study is successfully launched in a primary care setting, there is a risk of studies not recruiting sufficient patients with the result that studies can be cancelled, delayed, only partially recruited for, or are terminated midway.

Arguably, a key hurdle when recruiting patients for primary care studies is the traditional 'manual recruitment' method still employed by most health providers in primary care. This usually involves a member of the practice staff approaching a patient based either on their 'local' clinical records or using the patient's EHR data which identifies them as relevant for a particular study. In either method, the primary care team would use a standard invitation script, effectively a 'one size fits all' approach when engaging with the patient. This may be a disincentive for patients who do not engage automatically with 'template' research approaches. These harder to engage patients could be from any demographic group but are likely to affect more marginalised populations.

There is a growing evidence base to suggest that, particularly for ethnic minority populations in developed economies, there is a bias against their proper proportion in clinical studies. According to a recent US study published in Med, a clinical and translational research monthly journal published by Cell Press, researchers found that clinical trial enrolment remains "largely homogeneous". "Unfortunately, clinical trial enrolment in the US remains largely homogeneous, with the majority of participants being non-Hispanic white men. Despite efforts to increase diversity in recruitment for clinical trials, enrolment of racial / ethnic minorities in this nation has decreased over the past two decades," the authors wrote.[1]

Beyond ethnicity, there are other factors such as patients who are digitally excluded and those in troubled or chaotic situations such as drug addiction, domestic violence, homelessness or poverty. Equally, this may affect patients in socially or culturally marginalised communities or immigrant and some ethnic minority populations where language might be a barrier to access health services, and other hard to engage demographic groups. For example, a recent paper published by the UK-based King's Fund noted that in England, "There are health inequalities between ethnic minority and white groups, and between different ethnic minority groups." "The picture is complex," the authors said, both between different ethnic groups and across different conditions, and understanding is limited by a lack of quality data.[2]

Another challenge is that the EHR does not provide all the data needed to determine the eligibility of a patient for a study. For example, symptom severity may not be registered in the EHR with sufficient accuracy given the format of the records. In contrast, ARPs can extract deeper information on a patient's experience of a health condition through more substantive interaction with the patient via digital channels and data on a continuous basis.

Finally, traditional recruitment methods also rely on 'cold calling' of patients. In the traditional approach, the patient may not be prepared for the invitation to join a study and so may not respond as positively as they would, had they been given an opportunity to consider the request through a non-intrusive communication ahead of a more formal call or invitation letter. This may weaken their inclination to participate when they receive a call. ARPs also have

the ability to send automated SMS/texts branded to come from the clinician and so can help prepare the patient ahead of a call or other approach as to what participation involves, ensuring more receptiveness to the invitation when the approach happens.

How ARPs can help

A fully operational ARP is able to capture data remotely and directly from the patient, the patient's EHR and their clinician. It automatically links this composite data back to a clinical study's dataset (the overall data accruing from the clinical study), in doing so reducing the burden on clinicians and allied professionals who form the study site team. This is a significant benefit for primary care health providers and clinicians such as family physicians and GPs, reducing the time involved in clinical studies, safeguarding patient data, improving health provider oversight and contributing to a more empowered and safer patient experience. ARPs also open opportunities for 'time-poor' medical staff and practice nurses to participate in clinical studies to which they would not otherwise have been able to commit. Equally, it opens up opportunities for practices that have no heritage in research.

ARPs, when fully operational, help study sponsors find eligible patients more quickly and in greater volume, replacing traditional communications channels such as manual phone communication and paper-based correspondence with automated engagement channels that enable real time capture of data. The technology also assists allied health workers such as a practice's administrative and reception staff who are often the first contact point with patients. As mentioned, ARPs can automate important messages and deliver them to patients, appearing as if they originated from the practice team (similar to a 'white label' marketing approach where a contractor offers a service under the branding of their client) saving time for staff who would otherwise be the 'front of house' team members responsible for managing communications with patients.

These benefits combine to make clinical study participation and recruitment of patients by primary care health providers more viable. ARPs also enable primary care health providers to scale up the numbers of patients who participate in clinical studies. In part, this is possible because they enable tailored communications based on the target demographic. For example, the patient cohort required by a study could be based on age, gender, ethnicity or other profile. Data gathered by an ARP enables precision targeting to find the right patients for the right study.

This opens the possibility of hosting clinical studies across a larger number of research sites and creates capacity for healthcare providers to participate in more of these studies than would otherwise be possible. Patient consent is obtained through text or email via automated outreach on behalf of their recognised health provider, avoiding time consuming and slow hard copy correspondence and ensuring the patient recognises the message is from their clinician or practice team. More research is needed into patient experience and expectations – although some anecdotal feedback is emerging. For example, Geoffrey Taylor, a UK patient who had experienced using an ARP said: "It made me feel good that I was potentially helping others. Everything was easy to use and understand. It was a positive experience."

With ARP technology making it easier for primary care teams to engage in clinical studies, there is a further benefit in that many clinical studies involve payments by the study sponsor to the study site for the time and activity taken in support of the study, so potentially enhancing the income of a primary care health provider. It should be noted that the benefits ARPs offer apply whether the practice has heritage in research or has no track record in research at all.

Evidence base

There is a growing evidence base around the challenges that have historically hindered patient recruitment in primary care, although clinical studies and data on how ARPs perform relative to manual methods of recruitment are yet to be published given the recent emergence of the technology. Several academic studies have examined the failure or delay rate of clinical studies on grounds of patient recruitment. The UK Health Technology Assessment Programme reported in 2017 in BMJ Open that 45% of 73 HTC/Medical Research Council funded trials between 2002 and 2008 did not meet their recruitment number.[3]

Around the same time, a UK paper published in *Primary Care Respiratory Medicine (Nature)* which examined the participation rates of GPs in investigating the association between environmental exposures and exacerbations of Chronic Obstructive Pulmonary Disease (COPD) found significant reticence among GP practices to participate in studies because of the workload.[4] In the study, 82 practices were invited to participate; 56 (68.3%) did not take part and, of these, 15 (17.9%) indicated that either they had 'too much workload at present' to complete the study activities or there were 'insufficient resources' or there was 'not enough remuneration'. This effectively resulted in a loss of 2,073 (67.7%) patients who might otherwise have been considered in the study.

Case example – Closed Loop Medicine

Closed Loop Medicine (CLM) is a healthcare company focused on developing drug and digital combination products, secured by funding from Innovate UK Precision Medicine Accelerator, to run a clinical trial in partnership with Queen Mary University London for CLM's integrated precision care solution for patients with hypertension (high blood pressure). The clinical trial, called Personal COVID BP, will see up to 1,000 patients recruited for a study investigating whether a combination product that links a drug to a smart phone app can enable patients to personalise and optimise their therapy regimen to treat hypertension. Importantly, the technology in the study allows patients shielding from COVID-19 to control their blood pressure remotely in a home setting environment.

The company worked closely with the lead clinical team and used radio advertising to support recruitment but, given recruitment rates, CLM sought to improve patient participation further. The company approached uMed, with its Automated Recruitment Platform (ARP) technology, to increase and accelerate patient participation. uMed, working in partnership with Closed Loop Medicine and the team at Queen Mary University London, engaged patients on behalf of their recognised healthcare provider by text/SMS to invite the most appropriate patients to volunteer for the study, making it easier for the patient to give consent.

This ARP technology supported the acceleration of recruitment into the study and was key to the study hitting (and going beyond) recruitment targets. Through its ability to send individualised text/SMS and online messaging, the uMed ARP technology supported the acceleration of recruitment into the study and was key to the study meeting and indeed going beyond its recruitment target. This enabled CLM to recruit the most relevant patients needed to move the study into its delivery phase.

Patients recruited through this ARP platform found the process easy to navigate, allowing them the time to read the Patient

Information Leaflet, to look up the study and become more confident and familiar with the research without the need for further consultation with a research nurse. By enabling and providing patients with the platform to make an informed choice to take part in the study, this empowered them to feel in control of how they engaged with the clinical research. The study team at Queen Mary University London (QMUL) reported patients were more motivated and better informed than other channels. In the future, it is hoped that all patients will be given the same level of control and comfort in participating in clinical research so making a conscious choice to 'click the link' and agree to take part; it is also possible that the patient felt more empowered to participate in the study – however this is an area for further research.

Dr. Hakim Yadi OBE, CEO of Closed Loop Medicine, explained his company's experience of using ARP technology, "At Closed Loop Medicine, we are developing novel drug and digital combination products prescribed on a single label. We are working at the forefront of the convergence of life sciences and health care technology, so it is important to us to be able to robustly and quickly validate our approach with patients. We used an automated recruitment platform[5] to rapidly scale up and automate the recruitment of our clinical study, led by Queen Mary University London. Working in this way enabled us to scale and complete recruitment more effectively than traditional recruitment models – it was a simple integration for our team and the health professionals at Queen Mary University London and one which we will seek to engage with again."

Conclusion

ARPs make it easier for clinicians supporting 'study-eligible' patients to communicate with them with more tailored and individualised messaging at greater scale and with reduced workload for the primary care team. In bridging the gap between the patient and the clinical study sponsor, ARPs make it much easier to find and communicate with patients at scale, potentially reducing clinical trial costs by over half. With radically cheaper and faster studies, ARPs also enable more researchers to take advantage of more opportunities in primary care.

In summary, ARP technology has these benefits:

Tailored engagement and individualised approaches – so not a standard script and so may receive a more positive response from the recipient patient. Finally, the benefit in opening the opportunity to screen patients for symptom severity and engage patients with bespoke questionnaires. For example, issuing letters to older, less digitally engaged, patients explaining that they may receive a text message; and sending text at times for different demographics. For example, many older people who have a mobile/cell phone prefer to receive texts in the morning and younger people in the afternoon. ARP technology enables different text messages to be sent at different times.

Reduced workload – for primary care clinicians and allied health professionals when participating in a clinical study.

Scale and speed – a fully operational ARP has the ability to send 10,000 texts in one issue and reduces the time taken to reach patients.

Ability to issue 'from clinician' communications – where communications to patients are branded as from the clinician including texts and other communications on behalf of clinicians.

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Dr. Matt Wilson

Dr. Matt Wilson is a former accident and emergency doctor, anaesthetist and medical officer in the UK's Royal Marines. He founded the uMed platform in 2018, recognising the benefits to clinical research of automating key parts of the clinical study process by using electronic health record data. The platform is engaging with two million patients in approximately 200 primary care sites in the UK and will soon include some US health systems.