

AI IN HEALTHCARE

Assessing the Hype versus Reality



Charting the challenges in successfully creating
and deploying AI-based solutions

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INTRODUCTION

This white paper, written by Richard Jones, President and Chief Strategy Officer of C2-Ai, and Professor Martin Curley, has been prepared to support StayLeftShiftLeft10X. This organisation, led by Professor Curley, is dedicated to identifying and deploying technologies in healthcare that can deliver 10X improvements across one or more factors including patient outcomes, speed, workforce impact, cost etc. The biggest issues in healthcare cannot be fixed with marginal gains, hence the target of 10X improvements.

C2-Ai is an exemplar 10X organisation and Richard Jones is working with the StayLeftShiftLeft10X team to establish the 10X criteria and credentialing process for technologies.

SUMMARY

The AI hype train, fuelled by generative AI, is rolling at full speed with uncontrolled and unrealistic claims and hopes. However, the reality is that deploying AI-backed systems to make a meaningful difference in health and life sciences is incredibly complex with huge barriers to entry/ attention.

Established, credible and proven tech that has broad recognition will stand tall through the tornado of noise and hype. The reality of finite attention will eventually cut in and create a more thoughtful, selective and focused path for new AI solutions, just not for a while.

The paper will discuss the high-level issues for development, deployment and adoptability. It will drill down into detailed of some of the 'must haves' to succeed in digital health with an AI-related solution. In addition, a maturity model is proposed to help position the readiness of potential AI usage and illustrate barriers that will make it harder to achieve broad deployment. Critical issues are illustrated in Figures 1 and 2.



Figure 1 Summary - 8 Challenges facing the deployment of AI solutions in healthcare



Figure 2 The reality of what you need to implement AI in healthcare

What innovations will win?

To provide a context for overcoming the challenges, let's begin by considering factors that will help make it easier to get the attention, clinical support etc. needed to succeed in delivering a mass deployment technology in healthcare.

As a generalisation:

- Broad solutions that address multiple care pathways will beat (get more attention) than solutions focused on niche problems.
- 10X solutions will trump solutions delivering 2% improvements. The pain of adopting the latter will not be worth it.
- Solutions that hit 'hot buttons' in healthcare will get attention. Those that don't will struggle.
- Approaches that increase clinician screen time significantly are unlikely to take hold.
- Avoid disrupting clinicians (given the mass resignation, high stress levels and overload) as this will not be met favourably.
- Design the use and/or integration to minimize IT teams' time (they haven't got any spare - ever).
- Be up and running and delivering benefits in days (C2-Ai solutions are).

Data

| You need the right to use the right data in the right volumes to deliver accuracy and avoid bias

Access to data is in itself a difficult challenge. However, the volume of data needed is not simply what is sufficient to create an algorithm or allow generative AI to do its work. The data volume must also ensure that the solution can be shown to be free from bias. As an example, C2-Ai has processed 425m episodes of care from 46 countries. That is typically 100% of patients across acute care so represents a huge sample set with statistically significant correlation to the patient population. In contrast, the issue in skin cancer detection in dark-skinned patients highlighted the problem of smaller data sets and/or self-selection where part of the patient population is underrepresented.

The examples of software failing to act equitably across ethnicities etc. are becoming too common.

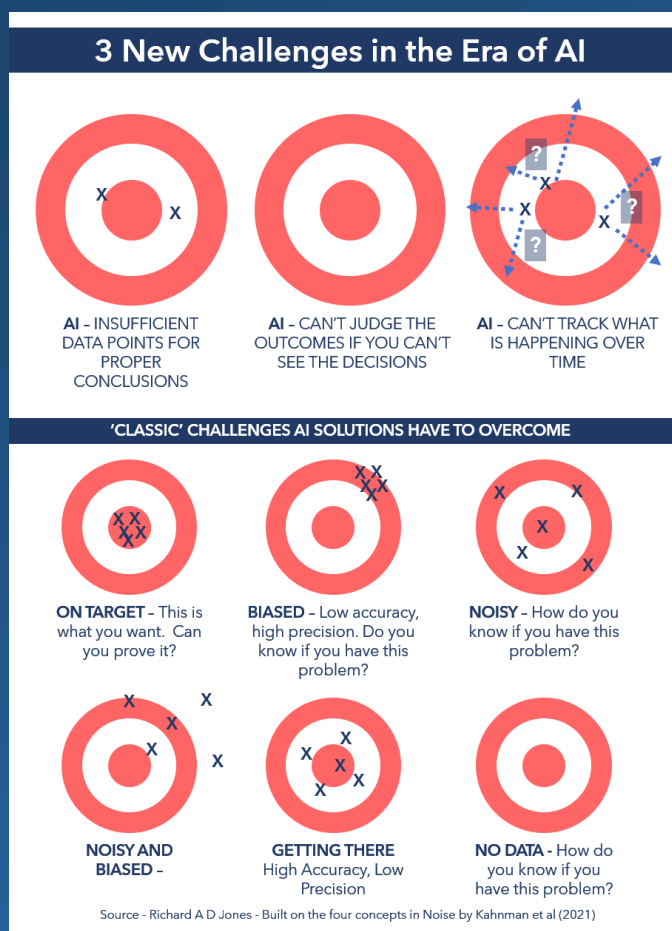
Layered on top of this issue is the opacity of decision-making in generative AI. This means it is harder to use traditional metrics like statistical significance of data and understand where the data has come from and whether its use is ethical and free from bias etc.

We're already seeing some push back on trusting company data in generative AI platforms, but this concern becomes a huge issue when you're talking about health data. Patients and hospitals might have trusted a company with the data, having passed through all the hoops above, but will they be happy about it passing into a 'big tech' platform.

The new generative platforms have no track record and trust will be hard to build. A good question is how do you trust that the data you input is within a ‘walled garden’ in a system as powerful as some of the latest generative systems. Can it be kept under control, or will it leak into development of other solutions? What happens when someone says cite the source and give me data examples?

We suspect there will be some serious missteps and data access issues that will create a big noise within the context of the general concerns about AI.

Algorithms



The diagram to the left shows some classic thinking about precision and accuracy.

Generative AI (in particular) raises some new questions about noise, bias, proof and stability.

The NHS and healthcare systems globally need accurate, precise, noise-free, unbiased solutions with enough data to avoid bias, and deliver certainty on the accuracy/precision.

The three new challenges relate to the opacity of the thinking and data usage of generative AI approaches in particular.

In addition, the tracking challenge relates to assuring results stay relevant with up-to-date data, and that you are aware if the AI is changing the outcomes. Companies may be optimistic they are keeping on top of accuracy and precision, but regulators and standards authorities are there to be sceptical.

References

| Risk averse clinicians need reassurance

It's simple. Without appropriate reference clients and papers, clinicians will be very wary about using a new solution. But that's easier said than done. The innovation will need to find a friendly hospital to carry out a trial and that's not easy in today's difficult healthcare environment. When hospitals are under financial and patient pressure, and are experiencing significant staffing challenges, it may take

months to find a hospital willing to cooperate, and then you have to run the trial itself which will add further months (at least).

Getting a trial potentially means you are dealing with an innovator or early adopter site, if considered against the innovation adoption curve. However, as Geoffrey Moore explained, moving from early adopters through to mass adoption is not straightforward at all. The risk aversion increases as you move from innovators through to laggards and so the evidence needed for mass adoption increases exponentially at each stage towards mass adoption.

Even post a trial, a solution is not sufficiently credible to get wide adoption. Clinicians and hospitals need reassurance about other deployments and reference hospitals will be needed in every new territory. Basically, the delay to acquire a trial agreement and then to get the results will repeat in each new country.

Credibility can then be enhanced with peer-reviewed publications, but these are likely to lag trials by some time as clinicians will need to be convinced about the efficacy of the solution before they begin any publishable work.

Finally, clinicians may start to provide personal references about the solution. This takes a long time typically due to the risk averse nature of clinicians as a breed and a desire to be absolutely sure before making such clear pronouncements on a solution. These are likely to lag the 'in country' trials by what could be years.

Overall, the time to get to a complete package of clinical and financial credibility around a solution is likely to be years.

Choking the innovation engine

| A new solution will need to get a place in the innovation pipeline

An innovation funnel acts as an engine for concepts, with tens or hundreds of ideas going in, and progress past discrete stages in the funnel dependent on specific criteria. The investment in time and company resources increases significantly as ideas pass each stage in the filtering process. A one-page idea may be enough at the start but if a company is going to make a \$100m bet, then that requires a business case, voice of a customer willing to take the product or service etc.

So the first challenge is getting attention with the company for the new concept. It will be fighting for finite financial and human resources and the criteria that were set previously may not suit an AI-backed solution. For example, if the innovation addresses something that has never been done previously or replaces revenue-generating activities for users (e.g. replacing an endoscopic procedure), there may be less positivity from the 'customer' base, or even downright hostility.

The onboarding process in healthcare providers and payers will be similar, with specific criteria and a desire to minimise time and resources spent on innovations that will ultimately not make it through to adoption.

So what's this got to do with AI? Well, the first observation is that the finite management bandwidth means the capacity for innovation is inherently limited. You might try to ram 1,000 new ideas into the funnel in either a company or a provider system, but it's simply going to stall. And if you try to upscale the innovation function quickly, you're going to create new issues trying get everyone up to

speed that will probably lead to bad decisions and a new overhead of complexity and communication trying to get this larger function to work effectively.

Overcoming friction

| When attention is a scarce resource, the biggest 'wins' will get more attention

This will be far from perfect in practice, but logically new applications must deliver truly compelling improvements to justify getting attention from both clinicians and also the other members of the 'buying unit'. That means managers need to understand the benefits also.

There are some 'qualifying criteria' that need to be overcome. Those include getting over inertia in busy clinicians and managers. Hence the need for the slam dunk benefits to make it worthwhile spending time on a new application. However, there will also be pushback on 'not invented here' grounds and internal teams that want to have a go at creating a solution themselves.

For new entrants into a market, they will also face incumbent operators trying desperately to maintain their position. That will sometimes mean competing with a single application that may be superior, but which is trying to displace a bundle of applications delivered by the incumbent supplier. It may also mean delays caused by said suppliers claiming they can do what the new application does.

Those are external issues that relate to the client hospital/payer. However, companies can create their own roadblocks if they are not careful. They need to avoid any adverse findings as they will provide ammunition to slow down any deployment, or even stop it completely. This is serious if it's with a client but critical if this happens during the initial proof of concept trial.

The team wants to have a go

| With the best will in the World, provider teams 'having a go' themselves rarely works

From a clinician perspective, trusting the IT team to come up with an accurate solution can be a big leap of faith. From an organisational perspective, it can be difficult to resist the 'easy answer' of the in-house team creating a solution. It's less 'distracting' than trying to evaluate an external solution.

However, experience of this shows there are serious issues with the in-house solution. These run from a lack of representative data within the organisation though to an inability to amortise the cost of development across multiple provider systems. Keeping systems up to date is also challenging for own developments because, as mentioned above, IT teams are already very busy with transformation, EHR implementations etc.

IT is a major bottleneck in providers

- | Minimise the IT time needed to support innovations in providers/payers, and avoid integration completely if you can

The deputy CEO of a New York provider system said that the waiting list for solutions to work with them was two years, even for those with an API. You'll have heard the IT teams that are flat out because they are doing a new EHR deployment and therefore can't even look at a solution. A CEO of a Baylor Scott White system in Texas told us that it wasn't even worth asking his IT team for anything before suggesting he'd pay for external resources to get things done.

If the IT team does have some time, then it's likely they will not align with the priority of the 'new thing' and so responses will take time and put delays into a development or onboarding process.

However, it's also worth noting that even a solution that is well received by the IT team, or comes from them, will not guarantee success. **If the clinicians are not supportive then the solution is dead in the water.**

Data security

- | Data security and governance is the heart of any solution

A singular challenge is to keep data secure. The level of scrutiny required both in North America and with NHS Digital, combined with the need for local storage, means significant resource and attention has to be paid to developing a secure environment. NHS Digital has a very rigorous approach, and their ultimate sanction is the company CEO ending up in prison. A sudden glut of companies seeking access to data sources will delay access and NHS Digital has been on a three-month hiatus from granting access due to an overload of their hard-working team.

So having the right data environment and processes is critical, but it is also vital to show that you can demonstrate adherence to these. Can you show what decision you made about a given risk and what information you used to arrive at that view? The level of detail needed is extraordinary.

Around the data environment, you'll need to have the right information management agreements, data sharing, HIPAA compliant hosting (in the US), medical grade data centre or equivalent, data management evaluations (DTAC), information governance and data privacy processes.

Standards and Regulation

- | Being AI-based doesn't mean an application gets a free pass from regulation

You can't just 'have a go' and assume that 'doing good' is a defence against having to meet appropriate standards and regulation

Among other simple issues, AI in healthcare has a direct impact on lives and quality of life. You can already see new applications appearing in healthcare and generative AI in particular will accelerate

that further. However, even some very large tech companies haven't noticed that they are delivering apps which constitute medical devices and so need to be regulated. Just because you hope something does some good doesn't mean it can be let loose into the World.

Companies need to comply with information management needs to successfully achieve (as applicable and likely after long processes), DCB 129/160, ISO 9001, ISO 27001, ISO 13485, CE/FDA Approvals. For some, overcoming the challenge of maintaining approvals while the AI changes underlying software and outputs will be very difficult (not a problem for mature and stable approaches like C2-Ai).

Converging at speed

| The end of differentiation and barriers to entry?

Strategic convergence is the idea that when everyone starts following the same business models and concepts, they will emerge with ever more similar strategies. One thing that mitigates this effect is the time to develop and launch new solutions. However, in the world where AI is now accelerating time to Minimum Viable Products (MVP's), will we see an end to true differentiation in the new markets AI can serve?

In reality, this is unlikely, but the pace of development may make it harder for smaller companies to innovate and maintain a barrier to entry, particularly in software, an area that is notoriously hard to patent.

The future is likely to belong to those companies that can get to a critical mass of deployment and credibility fast. Notwithstanding the many challenges in getting attention, securing trial sites etc., this may favour big tech companies that have the resources to back winning technology in comparison to those taking time and bootstrapping the new application.

A Maturity Model for AI

| Established solutions that have faced and overcome the challenges in Figure 2 will be in prime position for the future.

In order to evaluate new ideas in AI for healthcare, the following maturity model is proposed as a starting point for development of a broader approach.

For each line item, the solution should be considered against the criteria under innocence to excellence. The maturity is the last box that the solution meets as the criteria are reviewed left to right on each line. In other words, when reading across, the solution goes from meeting the criteria to not meeting them, then the maturity is the box to the left (the rightmost set of criteria met).

As an example, the maturity for C2-Ai's solution is mapped onto the maturity model. Many of the new concepts would meet only the respective 'Innocence' or 'Crawl' criteria. The full model is included as an annex at the end of this white paper for convenience.

	Maturity Level (work from left to right to last category that applies to the innovation/solution)				
	INNOCENCE	CRAWL	WALK	RUN	EXCELLENCE
Data	A concept but no data	Mid-size data set but uncertainty on bias	Larger data set with some aspects to reduce impact of bias	Large data set in one country only - designed to avoid bias	Data sets from all target territories - big enough to avoid potential issues of bias
Credibility	Clear concerns on use and security of data and/or ability to deliver in healthcare	Credible team in new organisation	No data security and usage issues perceived and some track record in the space	Good reputation in industry and working on overlapping area to current solutions	As left but solution provider seen as longstanding industry expert in the topic area
Impact	Niche problem Low down the pecking order of 'hot topics'	Clear benefit over existing approach in niche application	Significant leap forward in niche application	Game changer in one important area of healthcare	Addressing the biggest problems in healthcare
ROI	Marginal clinical advantage only but cost is multiple of existing approach	Clear clinical advantage but cost up to twice that of existing approach	Similar cost to current solutions and better than today's solutions	Business case with marginal ROI for deployment of the solution	Clear ROI including in US reimbursable (UK, Canada etc.) health systems (e.g. IMA, MHRA, MD SAP as necessary)
Standards	Uncertainty on standards/regulation	In process on getting necessary standards	Essential standards met to deliver solutions legally	Essential standards and some 'confidence' ones that will reassure potential clients	Full ISO, DTAC, FDA, IMA, MHRA, MD SAP as necessary
Clinical Buy-in	Seen as IT solution with limited clinician support and/or clinical workflows impacted and/or 'yet another dashboard' to try to make inferences from	Solution champions in clinical community developing but still seen as in 'early adoption' phase	Local champions for the solution established among thought leaders	As left but developing international champions and references	Championed by clinicians and leading institutions in multiple countries
Uniqueness	'Me too' product with obvious competitive approaches already in the market	Strong overlap to existing solutions	Partial overlap some but not all functionality areas	Minor overlap of full functionality to existing approaches	Globally unique approach deployable at scale
Advantage	Lower performance than current approaches and/or more expensive	Similar performance to solutions/approaches in the market	Clear differentiation in some but not all aspects	Significant differentiation	Delivers 10-100x benefits in clinical and financial terms
Onramp	Requires integration into multiple different systems (e.g. EHR) and/or Creation of new bespoke interface and and/or Multiple data source integration required	API link needed (have to await IT time which could be 2 years in one NY system)	Some interfaces in place but still rely on client IT team		No integration required or plus and play interface already defined
Workforce	Requires retraining and adds to burden of doctors/nurses	Neutral impact in deployment on workforce time but training overhead significant	Neutral impact on workforce time and easy onramp to switchover to this 'new way'	Reduction in workforce stress and/or workload for given case mix	As left but also no clinical workflows impacted in derivation of analytics and/or reduces workload through targeting of solutions and/or reduces workload through reduction of complications, faster throughput etc.

End Note

This white paper will be updated regularly, and the authors welcome feedback and ideas to build on the core concepts described above.

To get in touch and to learn more about StayleftShiftLeft10X, email r.jones@c2-ai.com.

ABOUT C2-AI

Sophisticated AI-backed fully automated analytics deliver a new level of precision on population health, clinical performance and outcomes - finding and resolving the 90% of cost/variation issues that hospital systems miss today. This means moving Medicare and Medicaid to breakeven, revolutionising payer economics and delivering population level risk-assessment into life sciences.

As an example of one application of the platform, C2-Ai's AI-backed prioritisation system for the elective waiting list is delivering significant NHS reported improvements – i.e. saving 125 bed-days per 1,000 patients, delivering an 8% reduction in emergency admissions and is capable of saving 20,000 surgeon-years time manually prioritising the list (at scale) £3bn+ and countless lives.

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