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Editorial

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Labs and Drugs

The delivery of high-quality healthcare and the effective treatment of acute and chronic illnesses cannot be achieved without drugs with high efficacy and safety and with laboratories working in the background to undertake basic research and understand the processes behind diseases, mechanism of action of different molecules and presentation of symptoms in patients.

Numerous drugs undergo the process of research and development, and only a selected few make it through the regulatory approval process. Drug development is an expensive and time-consuming venture, and the journey involves many steps and many people.

In this issue, our contributors discuss the importance of drug development in healthcare and the critical role of laboratories. They discuss the essentials of drug development, the importance of introducing advanced treatments that are safe and efficacious, strategies to prevent lab errors and the urgent need to address antibiotic resistance. They also talk about the role of healthcare data, the application of this data and other advanced technology to facilitate the process of drug development and the need for greater investment in research and new drug development.

Ekaterina Kldiashvili provides an overview of the types of errors in clinical laboratories and how the integration of eHealth approaches in routine practice could help reduce them. Maria Carrillo discusses the goals and vision of the Alzheimer's Association and the important role it plays in advancing vital research for the treatment, prevention and cure for Alzheimer's Disease. Samna Ghani discusses the global health issue of antibiotic resistance and explores why the pharmaceutical industry is not developing antibiotics.

In our Management Matters section, Paul Timmers talks about the importance of protecting European interests and sovereignty in health data innovation. In our Winning Practices, Henrique Martins provides an overview of a recent study for the Panel for the Future of Science and Technology and highlights the need for the European Union to use data more effectively to make data-supported public health policy proposals and informed political decisions. Meetali Kakad discusses digitally-enabled integrated care and highlights lessons and measures to increase the success of integrated care plans.

Renato Cuocolo is in the Spotlight in this issue as he discusses the challenges in assessing research quality in radiomics and highlights the transformative potential of radiomics for medical imaging.

We hope you will enjoy this issue. As always, your feedback is welcome.

Happy Reading!

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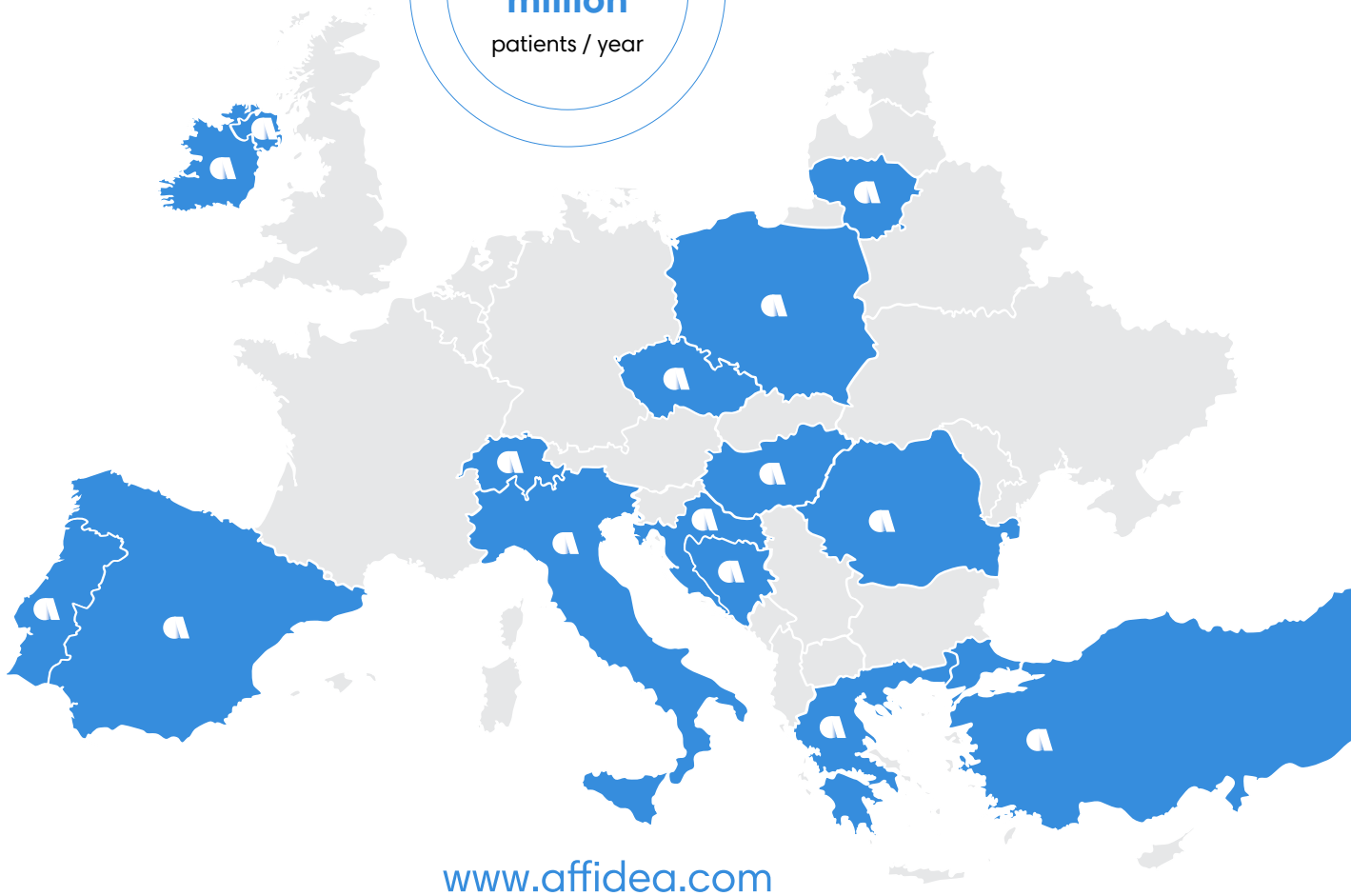

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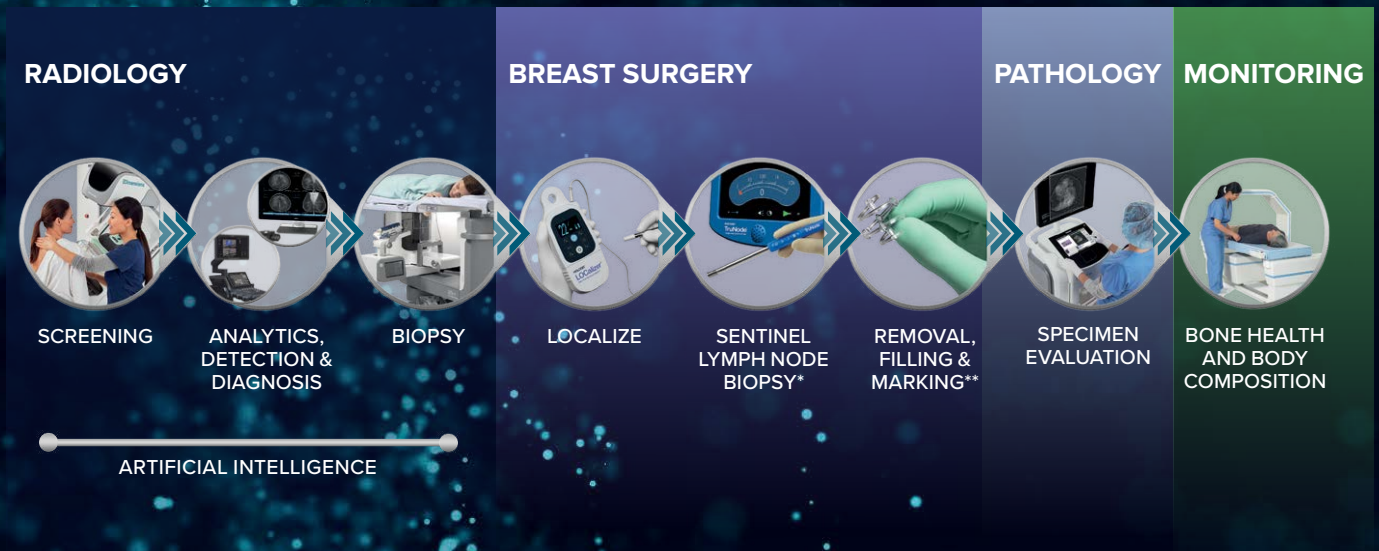

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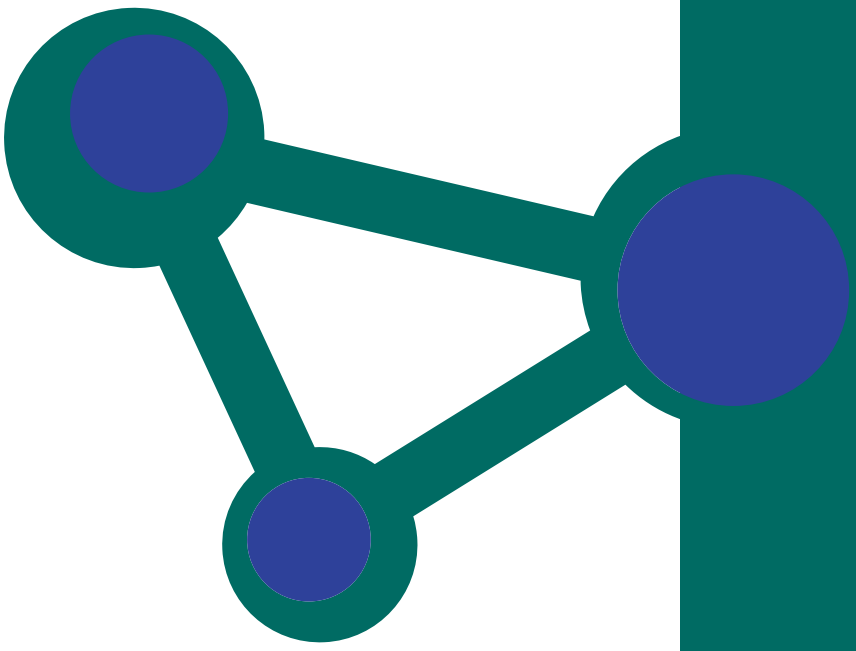

MANAGEMENT MATTERS

"Sovereignty does not mean that we do it all on our own. We are not in Fortress Europe. Of course, we work with others! But not unconditionally and not by naively putting sovereignty at risk." *page 442*

Health Data Innovation Perspectives

Author: **Paul Timmers I Research Associate, University of Oxford, Oxford, United Kingdom | Adjunct Professor, European University Cyprus I** Nicosia, Cyprus

Prof Paul Timmers at the University of Oxford and European University Cyprus speaks about the importance of protecting European interests and sovereignty in health data innovation.

Key Points

- Protecting health data as digital assets is vital for safeguarding European sovereignty.
- National health innovation policies should view the European Health Data Space (EHDS) as a sovereign asset.
- EU national innovation plans for health data innovations like digital twins and AI should benefit Europe.

Let me start at a fairly high level about future innovation with health data by addressing the political and policy dimension of sovereignty.

Over the past years, Europe's strategic autonomy has become Chefsache. This is because we feel threatened by other geopolitical powers and by the power of large digital platforms. It is worsened by the constant undermining of our economy, society and democracy by foreign states and cyber-criminals (Timmers 2018).

Strategic autonomy is about control to guarantee our sovereignty. And sovereignty is about our territory, people, values, natural resources, and digital assets. Health data are digital assets that belong to us: sovereign assets. Aren't they so for you personally and also for a country? We want to control our health data, who can access them, make money with them, use them for the common good. This is considered all part of health sovereignty.

Now sovereignty is not the same as resilience. The COVID-19 pandemic has indeed made painfully clear that we lacked health resilience in masks, ventilators, and hospital capacity. Health resilience is the capacity to withstand and recover from shocks and disturbances in public health. Health systems must keep running. But health sovereignty is about our freedom to determine our future in health. So, resilience is a necessary but not sufficient condition for sovereignty.

I mention this because we need to be motivated by both sovereignty and resilience when we design technology and laws. This certainly holds for the European Health Data Space for health innovation with data, the EHDS (European Commission 2021).

National health innovation policies should best see EHDS as a European sovereign asset. It is a triple win. One: each country on its own is too small, but together, they each get the full benefits. Two: the EHDS is a new asset owned by all Europeans. A richer Europe means more credibility of governments in the eyes of citizens. Thirdly, with a robust European health data asset, the EU has a stronger position in the world. Good for sovereignty. Good for resilience.

So we want control over health infrastructure, data, algorithms and apps. But we also need to share control. We do that by interoperability-by-design and sharing innovation across the EU. We must combine that with flexible EU legislative and governance frameworks that are favourable for Europeans. A national innovation plan without European interoperability should be a no go. And static EHDS legislation is no good either.

One more comment: sovereignty does not mean that we do it all on our own. We are not in Fortress Europe. Of course, we work with others! But not unconditionally and not by naively putting sovereignty at risk.

Briefly, a second point for future health data innovation. Science and technology have their own momentum. We want

the full benefits. I am inspired by the potential of AI combined with digital twins. Digital twins contain important information about your real self. In health, a digital twin is used to simulate and anticipate treatment effects like medication, therapy or even surgery.

With AI, we can combine data from many digital twins for better diagnosis and predictive treatment. Digital twins with AI are coming up in industrial, IT systems, and recently in the circular economy. By 2026 over 90% of all Internet of Things (IoT) platforms will contain some form of digital twinning capability (ResearchandMarkets.com 2021). EU-funded research on Virtual Physiological Human (VPH) was an early form of digital twins for organ models and surgery.

Personal health is now becoming par excellence the area for digital twins and AI. Of course, we want to deal with this intelligently. This means integrating policies to meet all requirements, including those on health, innovation, data protection, IT policy, and human-centred and ethical AI. It is a big and promising effort. So here too, our national R&I plans should join forces and align.

In summary, EU national innovation plans should contribute to health data innovation from the perspective that together we stand and divided we fall. That is divided we fall victim to other states and big tech. And they should jointly in Europe make a winner out of AI and digital twins for personal and public health.

Sovereignty does not mean that we do it all on our own. We are not in Fortress Europe. Of course, we work with others! But not unconditionally and not by naively putting sovereignty at risk.

Conflict of Interest

None.

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REFERENCES

European Commission (2021) European Health Data Space. Available from ec.europa.eu/health/ehealth/dataspace_en

ResearchandMarkets.com (2021) Digital Twins Market. Available from www.researchandmarkets.com/reports/5308850/digital-twins-market-by-technology-twinning#tag-pos-3

Timmers P. (2021) Debunking Strategic Autonomy, in EU Directions. Available from directionsblog.eu/debunking-strategic-autonomy/

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SPOTLIGHT

"There is hype for deep learning because it's more complex and it requires higher computing. It looks more glamorous"

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Radiomics: Recent Trends and Assessing Research Quality

Author: **Renato Cuocolo | Department of Advanced Biomedical Sciences | University of Naples 'Federico II' |** Naples, Italy

Dr Renato Cuocolo, radiologist and research fellow at the University of Naples 'Federico II', recently spoke at the 2021 European Society of Medical Imaging Informatics (EuSoMII) Annual Meeting about the challenges in assessing research quality in radiomics. Given radiomics' transformative potential for medical imaging, HealthManagement.org met with Dr Cuocolo to discuss the recent trends and challenges facing radiomics. Topics ranged from artificial intelligence (AI) integration into the radiological workflow, the appropriateness of specific machine learning algorithms, and assessing research quality.

Key Points

- Although AI can be applied to facilitate clinical workflow, challenging, high-concept aims drive radiomics research.
- AI can excel in prioritising patients to deal with heavy clinical demand and help with image review and interpretation.
- Radiologist-AI interaction should be seamless but not be based on blind adoption. Radiologist-AI trust can be built using easily verifiable outputs in the initial implementations.
- Despite the growing focus on deep learning, any correctly-applied machine learning algorithm can work well. Simpler models should be preferred if the performance is substantially equivalent.
- If the theory behind a radiomics investigation is sound, then performance should be reproducible under a variety of conditions.
- Most commercially available AI solutions do not have peer-reviewed data backing their performance claims.

What Needs Now Facing Radiology Can AI Address?

This is a challenging question. The potential for what we all aspire is to have radiomics and machine learning open new possibilities and give us new avenues to bring value to healthcare through radiology; to allow us to obtain information that currently is unavailable from the images, or are not easily obtainable, or require high levels of expertise.

In practice, in the short and medium-term, a feasible goal is to lean on radiomics and machine learning to help us improve the quality of life and speed up the repetitive and less interesting tasks. Consequently, radiologists can be more fully dedicated to the more challenging and interesting aspects of clinical practice.

For example, automated lesion size measurements, segmentation, with less focus on their characterisation; the last topic is still too challenging for widespread clinical adoption of predictive modelling.

Can AI Help Tasks That Are Inaccessible, Hard, and Tedious?

Yes. For example, there are multiple sclerosis lesion load comparisons over time or oncological patients staging or follow-up exams. These are tasks that already have some software tools available. Machine learning can certainly improve on those that are available, and this is already a reality.

In the long-term, with the development of the field, one would hope that we could use these tools to obtain additional information compared to what we currently can: for example, the genomic or phenotypical profiling of diseases, which we currently mostly cannot do. This is more interesting from a

research perspective right now because it's the furthest away from a clinical practice point of view. On the other hand, what is more interesting from a clinical practice point of view is these repetitive, boring, and time-consuming tasks that are not challenging for radiologists. Those are the ones that are less interesting from a research point-of-view, and maybe there's less incentive on publishing on those topics because they're less glamorous. One has less opportunity to have high visibility with those efforts.

Rather than the Tedium of the Workflow, What Is Driving the Innovation?

No, it's not driving the innovation, but I think it's where radiomics can find an easier application in the short and medium-term. What is driving the research are more high concept rewards, but those are more challenging to implement. I think those are where the attention is focused, but those applications are still very far in the future in a credible manner.

There is a disconnect between where the research is focused, where the funding is going, and where I think radiomics can make a short and medium-term clinical impact in the next five years or ten years. When you're modelling for genotypical aspects or similar outcomes, it's very challenging to reproduce the results across the board and have a product that is implementable everywhere in the world because the settings are incredibly different. Even when you develop a good product, maybe an institution will change their scanner three years in the future? Then you may have to start over pretty much. On the other hand, there are simpler tasks, like lesion segmentation, that are easier to verify from the radiologist's point of view because you can see and check the output in real-time. That's easier to implement, but it's less interesting. It's less glamourous from the research, academic, and funding point of view. It's more challenging to obtain an interest in research in that field. So, I think there is a disconnect between what can be done right now and what we would like radiomics and machine learning to do in the future.

How Have Radiology Departments Handled Increased Demands Due to COVID-19?

Yes, there was a high increase in chest x-rays and chest CTs in my department, but unfortunately, there was also a decrease in many other areas. The overall amount of activity increased but not too much. Our resources were focused. Regarding radiomics, I think they could not help speed up the reporting of these.

But machine learning in this setting could be useful in areas not tied to image analysis because machine learning also has some models and approaches to improve patient prioritisation and management of triaging and waiting lists.

Machine learning could have a role in addressing the increased demand for radiology due to COVID-19 or other future reasons where we would like to provide more exams. That space would require the digitalisation of healthcare databases providing information about the patients to correctly select which patients should have easier or earlier access to the exams.

That's a delicate and challenging topic, but it's a space where machine learning could help. It's something that's already done in other areas where machine learning has already been applied. They're less critical than healthcare, but there is good experience in this kind of work in other fields.

> If there's something real behind that experiment, then it should come up independently and from more groups – because there's something there that we're all looking at

Is One of AI's Best Applications Prioritising Patients?

Patient realisation and prioritisation of the exams will help manage the resources when the demand is higher than the resources. Machine learning can help in correctly distributing the resources to allow people who should access healthcare, radiology in this case, so that they won't be left out because there's too much demand.

How Can AI Help Improve Image Review and Interpretation?

Yes, it can help. To help clinical practice and imaging interpretation review, AI solutions should be integrated with the current software we already use for image reporting, such as PACS systems visualisation and reporting systems. Some solutions work together with PACS vendors and provide good integration with modules within the viewing system. In some cases, they are automatically filling up some of the parts of the reporting. This could be ideal because this software usually has a very practical application like lesion detection, measurements of lung nodules, brain aneurysms, or other findings. Volumes of

brain haemorrhage are easy for radiologists to double-check. We have its output integrated within our clinical workflow, and it's easy for us to see that the algorithm in these applications is working as intended. So, we can easily trust the output of the model. Focusing on these kinds of tasks eases the introduction of these tools in practice because it's easier for radiologists to trust something they can verify immediately.

When you have outputs that refer to information that has to be obtained after surgery, down the line, or prognosis after ten years, it's very challenging to trust the output by someone who doesn't know how the system works or hasn't worked on developing it. When it is outputted and integrated into a report, they have to sign and take responsibility for it.

Should AI Systems Seamlessly Integrate into the Workflow and Not Be a 'Black Box'?

I think interaction should be as seamless as possible. It can be done by not using external software as much as possible and not using a dedicated workstation as much as possible.

It should not be left confined to niche areas or specific experts only. It should be made as easily accessible as possible, so the interaction requires as little action from the radiologist as possible. It should be just an overview of what the output is. And use outputs that are easily verifiable by the radiologist without complex technical knowledge. That would be useful.

Should Radiologists See 'Behind the Curtain' and See How the Model Works?

Yeah, you have to see how the model is working. This is challenging because it's impossible in most cases, or the output needs to be easy to understand.

For example, I can see if the software detects a nodule and measures it. I can see what the measurement is and where the nodule is located. So then, it's easy for me to verify that it acted correctly, even if I don't know how it detected the nodule and how it performed the measurement. I see it's correct, and then I can trust it. That trust can build to introduce more complete tasks where we can start trusting it a little more, delegate, and step back.

This is a challenging balance because you don't want to get to the point where you let the algorithm work completely unsupervised. We want to trust, but not too much. We want someone to check what's going on. It's similar to what's happening in self-driving cars. It's something that has been promised for many years. Even now, there's lots of software, but they always require a driver who has their hands on the wheel. Even when the car is in perfect conditions on the highway with low traffic, supervision is always required. No one would ever suggest using the car without any kind of supervision. The same thing is applicable in healthcare and radiology. It's probably equally dangerous because it's always a life-and-death situation. In both cases, you can have a car accident or misdiagnose a lesion or not see a lesion and its secret features.

What is driving the research are more high concept rewards, but those are more challenging to implement

What Information Should AI Provide? What Are Useful Features?

Suppose one wants to dig into how the software works internally. In that case, this should be made as available as possible - for example, seeing feature distribution, seeing how the model is built. If the model uses specific features, it could provide some information on how these features have been distributed within the lesion and, maybe, on the training database where it was used. It should give some insight into how it arrived at its conclusion. For deep learning, you can have activation maps to see where the model's image detention was focused. If one wants to have some information, it should be available because there can be some doubts about the output.

But the front-end for the general user should be as simple as possible, so that information can be accessible but not be mandatory to look at it. It can get too complex for the general user. To become something that we use routinely, it should not get into this level of detail for every exam. Otherwise, it becomes a hindrance instead of perfection.

The ideal implementation depends on what we're talking about. For example, for prognosis, probably just having a probability and an outcome is useful, so we know the progression of disease in five years or something like that. But it would be pretty extraneous to what we usually report right now in radiology. It would not be easy to integrate this information within with what we are used to having in our final exam reports. That requires a little bit of work once these technologies are widespread.

Which Machine Learning Algorithms Lend Themselves Well to Radiomics?

Pretty much you can use any algorithm with radiomics, even if there is always a challenge tied to the number of patients or lesions or instances available for the training of the model. The main issue is that radiomics usually produce by definition

hundreds or even thousands of features for each case. It's known that in machine learning, like in statistics, one cannot use the whole data set because the amount of noise is excessive.

So long as there is a correct pipeline before implementing the machine learning model, there's a good feature reduction. This can include good feature stability, univariate analysis, multivariate analysis, dimensionality reduction with the principal component analysis, or even more complex algorithms. These could be considered machine learning algorithms but unsupervised ones. Then much any kind of model can be used.

in other tasks.

Deep learning models have reached prominence in other fields where data sets consist of millions of entries, while in radiology and medicine, we have tens or hundreds of patients. When we have hundreds of patients, we are already happy because we have a rich dataset for our field. But, if you compare those numbers with what is available, for example, in image-net or in other datasets, it's pretty much a drop in the ocean.

To summarise, all models can be useful if selected for the right task. One should start simple

Patient realisation and prioritisation of the exams will help manage the resources when the demand is higher than the resources

From a methodological point of view, if we can obtain a similar performance with a simpler model, it would always be preferable to start out using the simplest model available: even a logistic regression or a linear regression, and then build up from there. Simpler models should always be preferred when possible because the simpler model is easier to understand and to verify that it's working correctly.

As we increase the complexity of the model with ensemble approaches, as with random forests, which are still very understandable, or support vector machines, the complexity increases to the point that deep learning becomes can go to support vector machines that can get fairly complex with learning pretty much a black box. Interpretability becomes limited. You usually can improve performance, but you pay the price in terms of interpretability. So different models should be investigated, but we should select the simplest one for the final implementation, giving the results we wish. This leads to finding the best balance between accuracy and explainability. This is a real advantage of simple models as compared to deep learning.

Today, there is a tendency to go directly to deep learning for any kind of issue. This happens not only in healthcare and radiology but in research in general. There is hype for deep learning because it's more complex and it requires higher computing. It looks more interesting. In the beginning phases of research, there is a tendency to overshoot and go directly to deep learning rather than starting with simpler models, which would probably be more correct from a methodological point of view and even from a practical implementation view.

When comparing various models, I can say all of them can be useful. There may be cases where deep learning is indicated even if the amount of data that we usually have in radiology is not comparable to what is available for deep learning and move to complexity only, if necessary, after experimentation, and not start with deep learning because that's what the trend is right now in research.

When Is 'Deep Learning' Appropriate to Use?

Deep learning by design uses a large number of parameters. That's already an issue when the number of data from which those parameters are derived is small. It holds the risks of bias and unreliable results. You can also use deep learning on features that have been extracted by hand or by manual analysis of the image.

The use of deep learning has to be justified from prior experience. Or, one should also use a simpler model for comparison and to prove the added value of a neural network. Even when this has been done in other fields, deep learning was not always the best solution. Random forests or even logistic regressions in many tasks and other fields are still competitive. Only when the amount of data becomes overwhelming (and this has to be demonstrated experimentally), deep learning has the upper hand unequivocally.

In radiology, we have not yet reached saturation level with simpler models, so that deep learning is required to improve what you're currently doing. I think the results that are reported right now in many cases are still obtainable with simpler methods. More understandable results are easier to present and propose to those not directly involved in the field. One can then build upon those. Once large enough data sets are available, then deep learning could probably become viable for more complex tasks that are not yet doable right now.

Does the Algorithm Selection Depend on the Imaging Modality, the Organ Tissue, or the Disease?

Those factors can influence the selection of the model

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but mostly in terms of the availability of data. Because in some modalities, like X-rays, it's easier to collect very large databases, and usually, there should be less variation. For other modalities, like ultrasound, image characteristics can vary greatly even within a site. Because each operator uses different settings and this changes the way that the images are acquired. This can introduce biases that are not visible to the human eye but become relevant when analysing the images quantitatively.

In general, I don't think there is a direct correlation between a specific image modality or organ kind of lesion and a preferred machine learning algorithm. I think the choice of the algorithm depends more on the task that we have in mind because if we are talking about lesion detection, then an algorithm that works on the images directly. This type of algorithm depends, not much on the organ or modality, but more on the aim and the kind of data set we have to work with.

What Challenges Do You Face in Comparing the Performance of Different Algorithms?

There is no preferred metric, even if some specific metrics are more commonly used for some tasks. For example, in segmentation, the dice score is the same as the F1 score used in classification, and so on.

One of the challenges is that researchers often expect to report just the area under the receiver operating characteristic curve (AUC-ROC) or one metric used as the reference, especially those not with a medical background. Usually coming from a more technical background, they're used to tuning the machine learning pipeline to focus on a metric that becomes the reference used for tuning the model, its hyperparameters, and the whole pipeline.

This translates to a tendency to focus on a single metric and then report only that metric within their paper. In medicine, we are used to having more metrics available and even the tools to obtain additional metrics reported in the paper. This information is necessary metrics reported in the paper. Suppose one wants to obtain additional information or even allow format analysis and other types of studies that aggregate data differently; this information is necessary to perform those analyses. In my experience, we did perform two meta-analyses on machine learning papers. In both cases, we have to limit our pulling of accuracies to AUC data because the raw data of the test stress was not available. There is a widespread issue of not presenting the entirety of the obtainable results. That's the main issue.

Usually, researchers tend to stay more general and provide the AUC as a general accuracy metric, but then they don't always test more prospectively. This applies not only to a prospective study but to even an experiment of clinical implementation with a specific cut-off and providing, for example, a specific confusion future metric with true positive, false positives response. This would be more informative. From a clinical point of view, specific metrics gain different values based on the problem we discuss. If it's a screening program, we could accept more false positives if it means we are not missing significant lesions. Providing only the AUC gives us no information on that side of thing, so although we may know that the accuracy is good, we don't know the practical distribution of the patients. We might prefer a lower accuracy with a better negative predictive. But I wouldn't focus on expecting a specific metric from each paper. I think it's better to ask for as much information as possible because that's the only way to go forward and have reliable results and build trusted systems. As long as we're only providing one metric, it can always give the impression of being cherry-picked and selective reporting, which only feeds the doubts that some people have towards these techniques. In my experience, we did two meta-analyses on machine learning applications. In both cases, we have to limit our assessment to AUC data because the raw data of the test stress was not available. There is a widespread issue of not presenting the entirety of the obtainable results. That's the main issue.

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From a clinical point of view, specific metrics gain value based on the problem we discuss. If it's a screening program, we could accept more false positives if it means we are not missing significant lesions. Providing only the AUC gives us no information on that side of thing, so although we may know that the accuracy is good, we don't know the practical distribution of the patients. We might prefer a lower accuracy with a better negative predictive. But I wouldn't focus on expecting a specific metric from each paper.

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Should the Best Metric to Use in Comparing Algorithms Depend on Its Intended Function?

Even if it is the best metric, it's always a limited amount of information. One should always ask for as much information as possible; all the possible metrics that can be reasonably obtained without going overboard.

I don't mean that everyone who presents a single metric does so malevolently. As stated previously, this is especially understandable when researchers don't have a clinical background. You usually have to select one metric during validation that becomes the reference metric during the development process. There is a tendency for machine learning developers, engineers, and researchers to focus exclusively on that metric. But that metric alone, at the end of the process when one wants to hypothesise the clinic applicability of the result of the resulting model, does not give the full picture. Having the full confusion matrix, which is all the basic obtainable metrics, gives us a better picture and helps us understand if some problems were not obvious to the researchers. For example, because they didn't have the required clinical background or they overlooked it. It can happen.

In general, the solution is for the journals, the readers, the reviewers, to require that all the reasonably obtainable metrics are produced to allow a complete evaluation of the actual result fully.

How Do You Evaluate Other People's Research When That Info Is Absent?

Well, if I'm a reviewer, usually, I ask for the confusion matrix as a requirement for the assessment of the paper. If I'm a reader, as I said, we did perform two meta-analyses. And in those cases, we had no other choice but to focus exclusively on the AUC values because that was the only metric reported consistently.

This is not ideal. For example, we already know that magnetic resonance imaging has a high negative predictive value in prostate cancer. If I'm developing a model for detecting lesions, I would be interested in a model with a high positive predictive value because then that complements better what we're already able to do as radiologists. But that requires some expertise from behind the research or the availability of sufficient information to assess that point from a reader point of view if the paper has already been published.

But in any case, if it becomes standard practice to expect a thorough reporting of the results in these kinds of papers, the issue will resolve naturally over time. When that information becomes available, we can perform meta-analyses as we do in other fields using classical statistics. We have come to expect this degree of information from clinical trials, not using machine learning. It's not reasonable to not apply the same standards that we have always expected from the other fields and not apply them to machine learning. It's not as if because it's machine learning, we don't have to expect the same degree of information in the end result.

There is hype for deep learning because it's more complex and it requires higher computing. It looks more glamorous

To Facilitate Comparisons Across Studies, Should Researchers Present All Their Data Within Reason?

There will always be a limitation in machine learning because unless the model itself is available for implementation, with details on the pre-processing pipeline of the data, you will never be able to reproduce the result completely.

From the psychology reproducibility crisis, one of the concepts that have emerged is that reproducibility should not be limited to the reproduction of the experiment in and of itself. So taking the pipeline, taking the code in the case of machine learning, having the data set, clicking, and having the same result is useful, but it's of limited interest.

The idea is that if the concept behind the study is sound, if the idea at the basis of a prediction or a predicted model of a classification model or regression model is sound, one should obtain within a certain degree similar results even approaching the problem slightly differently. If the information is there for the exam type, for that lesion type (for example, if you're talking of oncologic patients as one of the most common applications), even if I'm not using the same method, if the theory is good behind this experiment, I should still obtain similar results because the information has to be there. Otherwise, if I am just modelling some random noise in my data set that's not present in your data set or another group's data set, then I would never be able to reproduce. If I give you my data and my model, you will be able to replicate my results. But those results may still not be true or not supported by a real theory behind the experiment. So we should present all the information to assess what's being produced by the model. Reproducing the specific experiment is only interesting up to a certain point. We should also aim to develop a more general understanding of what we're looking at in the images; what those patterns

mean. If there is a pattern that is informative in that lesion, then it should be informative regardless (within certain limits) of how I am looking at it, detecting it, or classifying it. That signal should be there.

In any case, we could have a more optimal solution that gains a little bit better accuracy or a less optimal solution that's less accurate. But if the information is there, it should still be evident even if we slightly diverge on the methods we're using.

So it's not the specific experience. It's more what's behind the experiment. If there's something real behind that experiment, then it should come up independently and from more groups – because there's something there that we're all looking at.

outcome or not. There should be a greater effort in building up a good theory behind some of the applications of machine learning - why it works for a specific game that we have in mind.

(To explain) There is a large amount of data on a specific outcome, such as prostate imaging, breast imaging, and neuro-oncological imaging. Some fields already have a large number of studies that have been published. But they're always very small and narrow in their overview. We should start having some works that try to aggregate this data and look at the bigger picture. And try to develop a larger theory within each of these areas of why radiomics works or doesn't work for something. This is very challenging, but in the long-term, if we want to make radiomics a robust field, it should have some theory and some understanding of how it works in a more general sense, not only because it works practically and empirically it stops there.

If there's something real behind that experiment, then it should come up independently and from more groups – because there's something there that we're all looking at

How Can This Strategy Address the Robustness and Replicability Crisis in the Literature?

From a more immediate point of view, we should raise the standards of what we expect from machine learning research in radiology. This process is already beginning because checklists have been developed by the editors and journals that are more specific to machine learning research than more general research checklists—these aid in ensuring that the correct amount of information is present in the paper. The includes the accuracy metrics that we talked about.

Also, there has been growing interest from various research groups, including my own, in using external tools to assess the quality of studies that have already been published. And the results of those efforts are usually not satisfying currently. The quality is generally found to be always very low across the board, independently of the application. There is a problem there. There is a small trend in improvement over the years, and we have to build upon that to obtain greater improvement.

In the short term, we have to continue raising the publication standards, especially on the more prestigious journals with the resources to implement more strict peer-reviewing. And maybe involve a technical editor for the more methodological aspects that may not be known to a clinical reviewer, that are usually involved in this process. Then from a more general point of view, we should develop the theory behind radiomics and machine learning.

For now, usually, research goes in this manner: You have an idea. You build a data set. And then you try, if you're able, to predict whatever you want to predict based on the idea that you had in the region. But only a few groups have tried to work on the specific reasons why a specific model works for one

Something similar happened for functional brain imaging and brain connectivity. And there have been other areas in radiology where initial results then brought building up a more robust theory for what's going on in the brain. It is possible to take a more practical aspect and quantitative results and experimental science. To build upon that to obtain a more theoretical understanding of what is happening biologically. I think that's what we should aspire to as machine learning researchers. It might not be possible, but we should try at least.

What New Directions Will Radiomics Take Within the Next Five Years?

In the next years, I think there will remain a high interest in radiomics for challenging tasks that radiologists cannot currently achieve: for example, genomic profiling, currently big profiling operations, and the prediction of outcomes at ten years. Research that's already going on right now will continue. I hope that there will be greater attention to the more practical side of things and more easily obtainable results that are clinically implementable and would allow for a real application of these tools in practice. Building trust between the radiologists and the tool, and the patient and the tool, will enable us to develop the necessary regulation and legal frameworks. Having simpler tools that are more easily verifiable will open the door for all the rest.

I hope that this realisation will become widespread. Not from academia, but from the companies? Working in this area, there

is already a greater understanding of how to move forward. For example, even from improving image quality and speeding up image acquisition in MRI or lowering the dose, those are applications of deep learning to which radiologists are less aware. Companies are investing much in things that are practical and visible. Verifying the image quality is still diagnostic, and the information that we can get from those images is still useful. There is a tendency to go in this way from a commercial view, which I hope will drive the rest of the field. The problems it will solve in the near future in the next five years will be more practical: like speeding up the acquisition of the burden of repetitive and ring tasks.

Do You Think That the Fear That AI May Replace Radiologists Is Justified?

Not really, because radiology is fairly complex and fortunately too complex for now to be substituted by an automated tool. If we're talking about if AI ever got to the point where it can substitute for radiologists, then there will be other issues to address; it will be able to substitute many other workplaces before radiology. There will probably be a reorganisation of society as a whole before that. In the field of medicine, other specialties are more immediately in danger from AI. For example, pathologists and other specialties that analyse images or also have these kinds of tasks. In that case, it's probably easier to develop tools that obtain similar results because it's more straightforward, and there's more homogeneity in the workflow. So I don't think that the fear is justified, even in the future.

As I said before, we are seeing what's happening even with self-driving cars. It's been ten years that self-driving cars are coming in the next five years. The hope and the expectations with AI are always too high compared to what it can do practically. Med students might not have sufficient knowledge both in radiology and in AI to correctly assess the situation. Until there is a shortage of radiologists, I would not worry much about it.

Will Demand for Radiologists Decrease Because AI Will Increase Their Efficiency?

No, I don't think so. Radiology is also becoming more and more active on the interventional side of things, so there's a whole side of radiology that's completely not interested in this problem. The current proposed applications of AI completely ignore the more practical side of things.

I think there is a greater chance that maybe teleradiology and other technologies might reduce or redistribute the work in radiology before AI can impact. Because of the tasks that AI can do, I expect a very limited impact on most of the work radiologists do in clinical practice in small centres. Most of the work that's done right now is aimed at higher levels of care and niche cases. Or even at increasing the number of exams that can be performed, which increases the demand for radiologists. Because if we can speed up MRI imaging from 40-minute exams to 10-minute exams or 5-minute exams, then instead of acquiring 20 MRI exams in one morning, we could acquire 100 MRI exams in one morning. Then we would probably need more people to report on those exams. I think it's very difficult to make predictions at this scale.

How Do These Algorithms Become Commercialised?

Well, that's challenging. You need solid computer science people and software engineers. Around the AI model, you have to develop a whole software infrastructure that allows for data management. Because you input raw data and feed it to the model after the correct prognosis, you have to implement the whole pipeline, developed in the research setting, the user interface, all the user experience aspects, and integrate it with the current solutions. The challenge is that it requires the involvement of many other people from different fields.

If you have an idea and a product, and you're able to trademark it and register it, you can go to a company and then use their expertise. For example, several medical scanners and technology vendors are already buying up smaller companies or are working together with researchers to develop their own different solutions.

In actuality, there is already a large amount of software that's commercially available for radiology. Recently, there has been even a repository with an accompanying paper published in European Radiology, including solutions already having either FDA approval and or European CE marking for medical use. So there is a large amount of software.

It's challenging for a research group alone. Probably it will never reach that point without either expanding in a start-up company and building up the necessary infrastructure or working together with a larger company that already has the necessary know-how.

Regarding the concordance between the research and the commercial aspects, this review highlighted how out of 100 commercially available solutions, most did not have any research supporting their performance. So, when they come to propose a product, most have no research. Of those with research (36%), only half of the research was vendor-independent, not directly authored or sponsored by the software vendor. While it's true that software is commercially available, it's probably not true that there is sufficient peer-reviewed evidence to support their implementation. We should see the actual quality of that research – if it's reliable and reproducible, and all the things we have discussed in our previous questions and answers.

There are commercially available solutions. Companies have come to my institution to propose some of these. I think it's still too soon to implement them. Maybe some of the vendor solutions to speed up image acquisition timing are already useable. For the rest, I would not invest any money in these solutions at this time as, most often, we will be early adopters.

In any technology, it's not always a good position to be in because the early adopters also end up being beta testers. They end up paying for the privilege of using something that's optimally ready. I would still wait a little bit more. If I had to spend money at my department and was head of that department, I would not invest in any AI products right now. There are still probably more viable expenses before spending that in that area for now. Maybe they'll be more mature in four or five years and have more evidence to support their use. For now, I think it should still remain mainly in the research field.

Don't the EMA or FDA Need Data to Approve the AI Solutions?

Most that have their approvals have it for technical feasibility, not based on clinical impact. They might have studies demonstrating that the results are reproducible and robust. It's not that they don't have any evidence. It may not be published, it's not openly available, and it does not undergo the classical external review process. They might have internal evidence that they may have produced to the legislative bodies. They can be used clinically, but most of them have no proven clinical impact.

Considering the United States, there's also a whole other discussion. In the last months, the first solutions have obtained the ability to be reimbursed by insurances. This is less an issue in Europe, because in Europe, usually, the final payer is, in large part, the state, at least, in Italy. There's always public coverage of most of the expenses. One of the questions is, who pays for AI? If it's valuable in Italy, the hospital pays for it. In the end, usually, it's the national health care system. In the United States, reimbursement is not so easy. It's a challenge for these companies trying to get recognition from insurance companies and be reimbursable. Translating the research to the technical practice, and especially on the commercial side of things, is a whole other world. It's very challenging.

I don't know if there are any implementations of 'upkeep over time' and guarantees that if the data distribution changes at your institution, the vendor takes care of this. Who takes responsibility if the model stops working? Who covers the costs, for example, of retraining a model on updated data? It never ends if you want to go into that side of things.

I am a believer in this technology. I think these technologies do work and can work and should be implemented in radiology in the future. It's just that probably, right now, we are going a little bit too fast. This can be counterproductive in the long term because we are riding the hype wave right now. If we proceed too fast and don't work as expected, we would have a backlash. It would be a long-term negative outcome because these technologies have solid bases and can be implemented correctly.

I do not wish to give the impression that I'm negative at all. I work mainly in this research area. It would be hypocritical of me to say I don't believe in it. I believe they work, but we should be very careful how we implement and develop this kind of research.

Conflict of Interest

Dr Cuocolo has reported no conflicts of interest.

Watch the full interview here. ■

COVER STORIES

"ALZ-NET will gather clinical data and outcomes from patients treated with FDA-approved therapies for Alzheimer's disease in real-world practice".
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eHealth for Morphology Laboratory Practice

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An overview of the types of errors in clinical laboratories and how the integration of eHealth approaches in routine practice could help reduce them.

Key Points

- At the practice level of morphology, errors can have a major adverse impact on patient care.
- There are different types of errors that can occur in a clinical laboratory.
- These include clinical errors, procedural errors, cognitive errors, and postanalytical errors.
- Errors in the preanalytical and postanalytical phases of testing probably have the greatest potential for serious patient harm.

Clinical laboratory tests and morphology (histology and cytology) diagnoses affect the vast majority of treatment decisions made by clinical physicians in nearly every medical discipline, impacting nearly every person seeking medical care. Many clinical laboratory tests are automated, performed by calibrated machines, reducing factors of human error and subjectivity. At the practice level of morphology, errors that can have a major adverse impact on patient care can occur anywhere in the classic test cycle.

In the preanalytical phase of testing, the morphologist must deal with clinical, specimen delivery, accessioning errors and mistakes due to incorrect specimen handling and inappropriate procedure of morphology laboratory. Clinical errors include the performance of the wrong clinical procedure, ordering of incorrect tests (e.g., inappropriate ordering of a frozen section), and the provision of erroneous, incomplete, or misleading clinical information. Specimen delivery problems include mislabelling of specimens before they reach the laboratory, placement of specimens in the wrong fixative or phlebotomy tube, untimely delivery of specimens, and specimen loss. Accessioning problems include specimen mix-ups at the time of log in, ordering of incorrect tests at accessioning, and computer entry errors. Specimen-handling problems include omission of important tests (e.g., failure to take fresh tissue for flow cytometry or failure to order culture) and ordering of incorrect tests. Errors in the morphology laboratory are many and varied, and include specimen and labelling mix-ups, undercutting or overcutting of tissue, poor cutting or staining of tissue sections, and cross-case tissue contamination (e.g., floaters). Although out of the direct control of the morphologist, many of these errors can directly contribute to or cause errors that a morphologist (pathologist/cytologist) will make and for which a morphologist (pathologist/cytologist) will be held accountable. These errors can cause very serious patient harm.

Errors in the analytic phase of morphology testing include procedural and cognitive errors in the gross room and procedural and cognitive errors at the microscope. Procedural errors in either venue include specimen mix-up and mislabelling of specimens or blocks and slide mix-ups during dictation of diagnosis at the microscope, that is, dictating a slide to the wrong report. Cognitive errors in the gross room include inaccurate examinations with poor descriptions (e.g., lack of appropriate measurements), lack of or incomplete lesion sampling, and lack of sampling of pertinent areas necessary for proper lesion characterisation or staging. Cognitive errors at the microscope include slips and lapses while analysing slides, poor cognitive formulations, knowledge problems, communication problems (e.g., poorly worded or unintelligible reports), and difficulties in using classification models that have poorly defined criteria.

Furthermore, it should be noted, that the practice of morphology involves the subjective interpretation of objective

data. The objective data, contained in the characteristics of the cells, organisation of tissues, and relationship to the organ on the whole, are preserved for the initial examination on morphology slides, within paraffin blocks, and, more recently in digital image archives. As morphology material is retained in a continuously observable format (the slide or digitised image), an important method of assessing the quality of morphology services is the use of second opinion "quality assurance" consultation. The consistent utilisation of such consultation to assess and report the diagnostic accuracy, completeness of information (clinical history and reporting of pertinent prognostic features), and consistency of terminology conveyed within each morphology report to clinicians and patients is but one measurement of quality performance in morphology diagnostic.

Errors can occur in the postanalytical phase of morphology diagnostics as well. These include untimely delivery of critical results, delivery of reports to the wrong location, and clinician misinterpretation of the final report. An error of this kind can cause a long delay in the treatment of a serious disease – a delay that can alter or be judged to alter the long-term prognosis of a patient. The error of the postanalytical phase is out of the direct control of the morphologist; they cannot be held legally accountable for it.

It is arguable what kind of errors cause the greatest harm to patients. Errors that occur in the analytic phase of the test cycle are probably of the greatest interest to the practicing morphologist because he or she is most directly responsible for and connected to these mishaps; however, it is by no means clear that these error forms fall within the realm of slips and lapses; and because they can be very difficult to detect, errors in the preanalytical and postanalytical phases of testing probably have the greatest potential for serious patient harm.

The application of eHealth technologies and the introduction of the concept of virtual laboratory in routine practice can be helpful in morphology diagnostics

The application of eHealth technologies and especially introduction in the routine practice the concept of virtual laboratory will be helpful in case of the morphology diagnostics. By this large, high quality, clinical databases will become available and be used for healthcare professionals' communication, distance consultations and education. This approach will facilitate:

- Timely delivery of tests and related reports;
- Analysing the reports, adding special marks for abnormal test results and providing reference values for the particular test without delay.

Therefore, while it may be impossible to completely eliminate errors, it is achievable and possible to reduce them through the integration of eHealth approaches in routine practice.

Conflict of Interest

None. ■

Dare to Change!

Author: **Roland Kuffer I CIO I Chem Hospitalier Emile Mayrisch I** Grand Duchy of Luxembourg
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An overview of the successful collaboration between Centre Hospitalier Emile Mayrisch (CHEM) and Agfa HealthCare and the implementation of the Enterprise Imaging platform.

The Centre Hospitalier Emile Mayrisch (CHEM) is the biggest hospital in the southern region of the Grand Duchy of Luxembourg. 1861 staff and 258 doctors work across three sites to care for 100,000 patients per year. But from an information technology perspective, it is a single hospital.

CHEM has been using Agfa HealthCare's RIS/PACS solution for 25 years. As Roland Kuffer, CIO, describes, "we were one of the first! And we have collaborated with Agfa HealthCare all these years, working together to always push the envelope further. As part of this, over time, we became increasingly convinced of the advantages of transitioning from the dual RIS/PACS solution to a unified Enterprise Imaging platform. Any functionalities we implement at one site, should be available at all three sites, directly and seamlessly."

The final decision to transform to Enterprise Imaging came after a very thorough workflow analysis from order placement, scheduling, RIS functionality to embedded result distribution in the EHR.

"We had to be sure that all of the workflow elements, functionalities and interfaces between the different systems could be replaced by the Enterprise Imaging platform. Once we knew we would not lose any of this, we very quickly made the final determination to make the change," describes Mike Moes, PACS Manager at CHEM.

The contract was signed at the very end of December 2019, and installation of Enterprise Imaging began in March 2020. "Of course, this timing created some unexpected challenges, but no project goes entirely as expected, so flexibility between stakeholders is critical," describes Mr. Kuffer.

A Single Workstation For Each Persona

The benefits of the unified solution were quickly felt at every level: from doctors and technicians, to administrative staff, to IT and PACS administrators, explains Mr. Kuffer. "Each different type of user, or 'persona', has their own, dedicated desktop. To give an example of how this makes a difference, with a RIS/PACS, the technicians get the worklist from the RIS, but they cannot see the patient's previous exams there: that requires the PACS. With our Enterprise Imaging, both the worklist and access to previous images are provided from the same platform, on one workstation."

Secretaries also have a dedicated desktop with their worklist, which was previously in the RIS, but is now on the consolidated enterprise solution.

For the doctors, Enterprise Imaging has also resolved the inefficiencies and difficulties of the RIS/PACS dichotomy. Mr. Kuffer points out that, increasingly, the clinicians' requests for imaging must be validated by a radiologist. "This is quite difficult to streamline in a traditional RIS/PACS set-up: the doctor must do one action in the RIS, and another in the PACS.

But with Enterprise Imaging it is very easy: the radiologist can validate the request and transform it into an order on a single workstation, even for more complex exams such as those using ionising radiation. You can define a different workflow for every type of exam, if you want. One radiologist can validate the exam request, another can interpret it. Enterprise Imaging is very flexible with workflows: any set-up you want is possible."

Another important advantage is that administration is simplified for the PACS administrator, thanks to the single console for handling interfaces, troubleshooting, managing the system setup, and more.

One-Click Images: XERO Seamlessly Integrated in the EHR

To further enhance the efficiency of the workflows and extend this advantage to the clinicians, CHEM decided to integrate the Agfa HealthCare XERO universal viewer deeply into the EHR, giving greater relevance to imaging information by placing it in the context of the patient's record.

"Often, the XERO viewer is integrated in the EHR at the patient level, but we wanted to push things further. By integrating it at the exam level, our clinicians can now open the relevant exam in the viewer, with just one click access directly from the EHR. This decision required a bit more work during

Centre Hospitalier Emile Mayrisch

the implementation of Enterprise Imaging, but will offer long-term benefits," describes Mr. Kuffer.

A Consolidated Platform That Reduces Total Cost of Operation (TCO)

In parallel to the benefits felt by the users, other advantages are more strongly experienced 'behind the scenes'. "Having a single platform that consolidates servers, interfaces and systems simplifies installation and maintenance, saving the IT team a tremendous amount of time and effort," explains Mr. Kuffer. "With the RIS/PACS, just installing one workstation required configuration with the RIS, the PACS, the Speech functionality – that last one could take hours! And whenever there was a problem, we had to determine if it came from the RIS, PACS, etc. So there were a lot of analyses to do.

With Enterprise Imaging, installing software or setting up a new workstation is much easier. And with a single overview, we can quickly determine the cause of the problem and fix the configuration. So even though there are more servers now, we can see everything on a single desktop; it's much more manageable."

As Mr. Kuffer describes, with Enterprise Imaging, no broker is needed between the RIS and PACS, so from three systems, they have moved to one. "That means one installation, one client, one configuration – the advantages are undeniable!"

Reaching Beyond Radiology: Clinical Pathways

The advantages of Enterprise Imaging reach far beyond the radiology department. "With Enterprise Imaging, the PACS is no longer an isolated island; instead, it is in the centre of the village, supporting our clinical pathways. For a wide range of the specific patient cases a set of different actions for lab, medication, care and radiology are predefined. Radiology plays an important part in the smooth workflow of the care path. "

He describes, "In our emergency department, we have created a dashboard showing the status of radiology and laboratory exams. Staff can see, on one screen, the status of all exams ordered for the patient: when they begin, when they are finished and when the report is available. In most hospitals, emergency department staff have to call around to see where anything is. But with Enterprise Imaging, we have all of the information needed, in one place. Enterprise Imaging communicates all the exam statuses via HL7, for the integration of a consolidated view of our emergency department."

He continues, "Furthermore, like many hospitals, we use a third-party endoscopy modality, and the relevant data is kept in an endoscopy documentation system. With Enterprise Imaging, all of the data and reports are available in one platform, which means that the clinicians can view both conventional radiography and gastrocolic images using XERO. In the same way, they can access ECGs, for instance. This fits with our vision of integrating the imaging data from all image-creating departments across the hospital into Enterprise Imaging, and making it available to our care professionals through the patient record."

Informed Decisions

Using the unified platform has also enabled the hospital to standardise its use of the Business Intelligence tools. "We were already using Business Intelligence in our previous system to

monitor the performance of the departments. However, there were a variety of individual analyses being made ad hoc.

With Enterprise Imaging, everyone can go through the same interface, which enhances control and cohesion, making it easier to optimise our processes and take informed decisions on, for example, investments," he describes.

implementation planning, especially as the Agfa HealthCare team could not come to the hospital. However, they remained directly accessible to us; whenever we had a question or problem, we could contact our technical support team. That was critical to the success of the project," describes Mohamed Reguieg, PACS Manager for CHEM.

With Enterprise Imaging, we finally have a truly single, unified system. This is the logical step hospitals have been waiting for

Close Collaboration Between Imaging, IT and Agfa HealthCare

"There are two particularities about our project that I believe played a big role in enabling it to move as smoothly as it did, despite the global COVID-19 pandemic. Firstly, is our very strong implementation team within CHEM. The other is the close partnership we have with Agfa HealthCare.

At the hospital, the PACS team is fully integrated in both the imaging and the IT worlds, forming a bridge between the two. "Mike and Mohamed's knowledge of both sides of the equation enabled us to jump over several hurdles, and to make certain decisions during implementation more quickly," says Mr. Kuffer.

"I'm very proud of my entire team, including those responsible for interoperability, and those who installed and configured the PCs. The migration was a joint effort that required careful and correct planning. There were a lot of interfaces with the PACS that disappeared from one moment to the next, so close coordination between imaging and IT was critical to maintain normal hospital functioning without disruption."

"The COVID crisis impacted – at the last minute! – our

Daring to Change

While Mr. Kuffer considers Enterprise Imaging the 'logical' step for hospitals, he sees it as even more: an opportunity to disrupt processes and evolve into a next-generation healthcare provider.

"When you have been working with one system for 20 years, and you have the chance to use something new, it's a big step. You have to take the time to question and re-evaluate your processes. Don't just try to adapt the new solution into what you have been doing: explore what you can do more with the new system, evaluate the possibilities, and adapt your workflow to that. The world has changed, and your processes shouldn't be the same as 20 years ago."

"Of course, change management in the organisation is important: it isn't easy to turn your back on those 20 years of familiar processes! To facilitate the change, we set up a steering committee that met every week, and as I said before, having PACS managers with one foot in radiology and one in IT was a big help. But in general, I find that once people have time to get used to the new system and way of working, they never want to go back to the old way. So dare to change!" ■

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We cannot wait to welcome you back in January 2022!

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Together for a healthier world

Working Towards a World Without Alzheimer's and All Other Dementia

Author: Maria C. Carrillo I Chief Science Officer I Alzheimer's Association I USA

An overview of the goals and vision of the Alzheimer's Association and its commitment to advance vital research for the treatment, prevention and cure for Alzheimer's Disease.

Key Points

- The Alzheimer's Association is a leading voluntary health organisation in Alzheimer's care, support and research.
- The Alzheimer's National Registry for Treatment and Diagnostics (ALZ-NET) will gather clinical data and outcomes from U.S.-based patients treated with FDA-approved therapies for Alzheimer's disease in real-world practice.
- The Alzheimer's Association is focused on increasing public and private investment in research and is the world's largest non-profit funder of Alzheimer's and other dementia research.
- Since its inception, the Alzheimer's Association's Part the Cloud initiative has raised over $60 million for Alzheimer's research, awarding grants to 59 clinical trials, which have gone on to receive $940 million in additional funding from other sources.

What is the mission, vision and goals of the Alzheimer's Association?

The Alzheimer's Association leads the way to end Alzheimer's and all other dementia — by accelerating global research, driving risk reduction and early detection, and maximising high quality care and support. The Alzheimer's Association is the leading voluntary health organisation in Alzheimer's care, support and research.

- Our Vision: A world without Alzheimer's and all other dementia®
- Our Mission: The Alzheimer's Association leads the way to end Alzheimer's and all other dementia — by accelerating global research, driving risk reduction and early detection, and maximising quality care and support.

The Alzheimer's Association works on a national and local level to provide care and support for all those affected by Alzheimer's and other dementias. As the largest non-profit funder of Alzheimer's research, the Association is committed to advancing vital research toward methods of treatment, prevention and, ultimately, a cure. Finally, the Association is the leading voice for Alzheimer's disease advocacy, fighting for critical Alzheimer's research and care initiatives at the state and federal level.

What is the objective of The National Treatment and Diagnostic Alzheimer's Registry?

The Alzheimer's National Registry for Treatment and Diagnostics (ALZ-NET) will gather clinical data and outcomes from U.S.-based patients treated with FDA-approved therapies for Alzheimer's disease in real-world practice. ALZ-NET aims to monitor and report clinical and safety endpoints for patients treated with FDA-approved Alzheimer's disease therapies, including accompanying diagnostics, to track the long-term outcomes associated with these therapies in a real-world setting.

The Alzheimer's Association, American College of Radiology (ACR), American Society of Neuroradiology (ASNR), and the Department of Biostatistics, Brown University School of Public Health will partner to lead this important initiative. The scientific team will include a diverse group of leading academic experts in Alzheimer's clinical research and care, biomarkers, clinical trials, biostatistics and implementation research. Registry leadership will work with industry stakeholders and payers in developing and implementing the registry.

ALZ-NET will gather clinical data and outcomes from patients treated with FDA-approved therapies for Alzheimer's disease in real-world practice. ALZ-NET aims to monitor and report

clinical and safety endpoints for patients treated with FDA-approved Alzheimer's disease therapies, including accompanying diagnostics, to track the long-term outcomes associated with these therapies in a real-world setting. To that end, ALZ-NET will:

- Collect and archive diagnostic and safety neuroimaging studies, as well as genetic and fluid biomarker data and biosamples.
- Broadly share de-identified data with the research community and other stakeholders.

coverage for the scans, stating "the evidence is insufficient to conclude that the use of positron emission tomography (PET) amyloid-beta (Aß) imaging is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of … Medicare beneficiaries with dementia or neurodegenerative disease."

CMS did find sufficient evidence that the use of PET Aß imaging is promising: (1) to exclude Alzheimer's disease (AD) in narrowly defined and clinically difficult diagnoses, and (2) to enrich clinical trials seeking better treatments or prevention strategies for Alzheimer's. Under the National Coverage Decision, Medicare provides coverage for one amyloid PET scan per patient enrolled in an approved clinical study.

ALZ-NET will gather clinical data and outcomes from patients treated with FDA-approved therapies for Alzheimer's disease in real-world practice

When you say this registry will be an FDA-approved-agent agnostic approach, what do you mean?

ALZ-NET will be designed to grow with scientific and medical advancements, and will be open to all FDA-approved Alzheimer's treatments. ALZ-NET will be a non-randomised, observational, multi-site, registry with an expandable platform that allows the addition of all approved drugs.

The registry will collect routine clinical practice data from healthcare providers. How do you plan to execute this? What would be the criteria for selecting the data sources?

ALZ-NET will leverage the Alzheimer's Association network of providers developed for the IDEAS and New IDEAS studies. We will provide educational support for clinicians in appropriate use of therapies, biomarker interpretation and safety monitoring. ACR and ASNR will provide education on PET and MRI interpretation for diagnostic and safety imaging studies.

ALZ-NET will recruit and collect longitudinal data through physician-submitted case report forms and payer claims, and will include collection and archiving of neuroimaging studies and biosamples. We will:

- Develop a multi-site network for patient enrollment and data collection.
- Collect baseline and longitudinal participant data, including measures of cognition and function and information about adverse events.
- Track health outcomes and resource utilisation via claims data.

Can you tell us a bit more about IDEAS (Imaging Dementia-Evidence For Amyloid Scanning)?

The original IDEAS Study was developed in response to the 2013 Centers for Medicare and Medicaid Services (CMS) National Coverage Decision on amyloid PET imaging in dementia and neurodegenerative disease. CMS did not provide

The Alzheimer's Association decided to lead an initiative to bring stakeholders together to develop a Coverage with Evidence Development programme. The IDEAS Study team was formed and protocol development began. The study opened in February 2016 and concluded recruitment in January 2018. The study engaged 946 dementia experts, who recruited Medicare beneficiaries from 595 dementia clinics and referred the subjects for imaging at 343 PET facilities across the United States. In total, 18,295 Medicare beneficiaries aged 65 and older meeting appropriate use criteria were enrolled into one of two sub-groups: (1) progressive, unexplained mild cognitive impairment (MCI), and (2) dementia of uncertain cause.

The IDEAS Study provided the strongest Phase IV data to date supporting the clinical utility of amyloid PET scanning. Results were published in JAMA in 2019 (Rabinovici et al. 2019).

Building on the momentum of the IDEAS Study, the Alzheimer's Association and the American College of Radiology, with manufacturing partners Eli Lilly and Co., GE Healthcare, and Life Molecular Imaging, launched the New IDEAS**: Imaging Dementia—Evidence for Amyloid Scanning** study.

The goal of the New IDEAS study is to determine if using a brain amyloid PET scan helps clinicians provide a more accurate diagnosis and make better treatment decisions, which would then inform or change a patient's treatment plan and improve their quality of life.

The New IDEAS study aims to be among the most racially and ethnically diverse Alzheimer's disease studies ever launched. At least 4,000 of the planned 7,000 New IDEAS participants will be Black/African American and Hispanic/Latino, populations historically underrepresented in dementia research. Participants will be enrolled over 30 to 36 months at 350 sites throughout the United States.

The vision of the Alzheimer's Association is a world without Alzheimer's and all other dementia. How will the Association make this happen, and what are your key strategies and future plans?

The driving force behind the Alzheimer's Association International Research Grant Program is our desire to improve quality of life for people affected by Alzheimer's. At present we are focused on increasing public and private investment in research and expanding our position as a respected global leader and the world's largest non-profit funder of Alzheimer's and other dementia research in order to accelerate progress toward our vision.

Together with our philanthropic partners, we are ensuring a profusion of new and diverse perspectives and cutting-edge projects to continue filling the drug development pipeline. The Alzheimer's Association International Research Grant Program lies at the heart of our commitment to advance Alzheimer's research. Since awarding our first grants in 1982, the Association has grown into the largest private, nonprofit funder of Alzheimer's research. In 2021 we made our largest-ever total commitment in a single year. Our active commitments now total more than $250 million, and they are powering more than 750 best-of-field projects in 39 countries.

The Association works to identify and fund a wide range of the most promising projects, from basic discovery science to studies addressing social and behavioural aspects of Alzheimer's and all other dementias. The studies we've invested have enabled significant advances across the research spectrum in areas such as diagnosis, genetics, treatments, prevention, early detection and enhancing quality of life.

Since its inception, the Alzheimer's Association's Part the Cloud initiative has raised over $60 million for Alzheimer's research, awarding grants to 59 clinical trials, which have gone on to receive $940 million in additional funding from other sources. With 100 percent of the proceeds from Part the Cloud going directly to Alzheimer's Association research efforts, Part the Cloud funding allows the Association to propel bold, high-reward research aimed at uncovering underlying brain cell changes, timely diagnosis and new treatments for Alzheimer's and all other dementia. In 2019, Bill Gates partnered with Part the Cloud and raised $10 million to help further the cause.

Modifiable risk factors are estimated to contribute to nearly four in 10 dementia cases globally, and the Association is leading and funding studies in multiple countries to evaluate lifestyle interventions designed to reduce risk of cognitive decline. This includes the U.S. Study to Protect Brain Health through Lifestyle Intervention to Reduce Risk (U.S. POINTER), the world's largest clinical trial testing whether multiple risk-reduction strategies can protect memory and thinking in cognitively unimpaired older adults at increased risk of developing memory decline and dementia.

The Association works to identify and fund a wide range of the most promising projects, from basic discovery science to studies addressing social and behavioural aspects of Alzheimer's and all other dementias

To foster collaboration and facilitate the sharing of ideas and data across the globe, the Alzheimer's Association has been increasing the number of research events we host worldwide. In addition to the Alzheimer's Association International Conference® (AAIC®), the world's largest and most influential international meeting dedicated to advancing dementia science, we now offer Neuroscience Next, AAIC Satellite Symposia, the Latinos & Alzheimer's Symposium, the Tau Global Conference and more.

In partnership with the Alzheimer's Impact Movement (AIM), a separately incorporated advocacy affiliate, the Association is the leading advocate for increasing federal funding for dementia research. Thanks largely to our leadership, Congress has been increasing the National Institutes of Health's (NIH) annual budget for Alzheimer's and other dementia research. It now stands at $3.1 billion, a more than seven-fold increase since 2011.

Research funding and scientific collaboration fuel medical progress. They have changed the trajectory of heart disease, HIV and many cancers, and they will drive progress toward our vision of a world without Alzheimer's and all other dementia.

Conflict of Interest

None. ■

REFERENCES

Rabinovici GD, Gatsonis C, Apgar C et al. (2019) Association of Amyloid Positron Emission Tomography With Subsequent Change in Clinical Management Among Medicare Beneficiaries With Mild Cognitive Impairment or Dementia. JAMA, 321(13):1286-1294.

Peer Review System: Collaborative Learning to Achieve Clinical Excellence in a Multinational Healthcare Provider

Author: **Alessandro Roncacci I Senior Vice-President I Chief Medical Officer I** Affidea Group
Author: **Nasia Papachristodoulou I Director of Clinical Governance and Quality I** Affidea Group

An overview of Affidea's Peer Review system that allows radiology teams to learn and grow together and benefit from each other's expertise and experience for better clinical outcomes.

At Affidea, we aim to create a strong culture of quality where every member of the clinical team feels empowered and encouraged to participate in the process of improving patient care. We do this through various systems and processes like Peer Review or Affidea's Learning from Excellence System (ALES) that we put in place in order to ensure that clinical voices are heard and that we learn from each other and never stop looking for improvements.

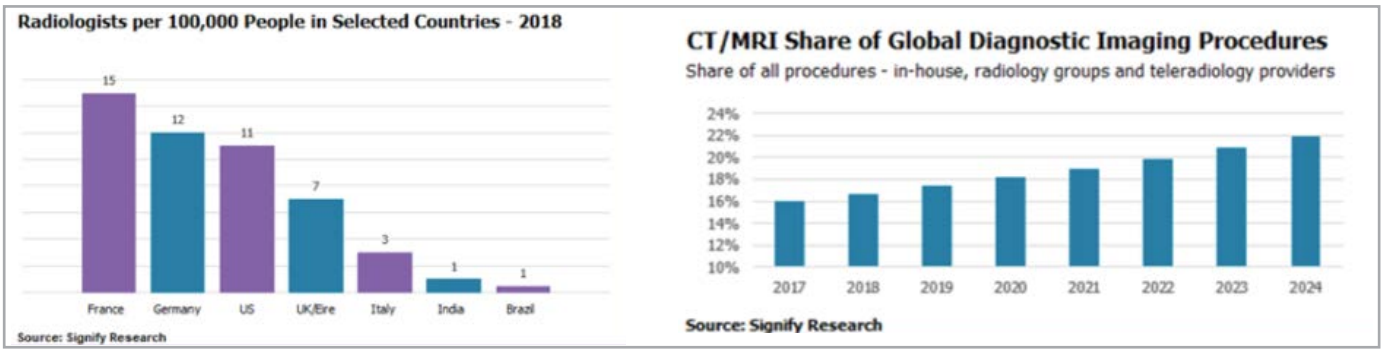
The Peer Review system that we put in place at Affidea is not used as a parameter for an Ongoing Professional Practice Evaluation, but to ensure high quality and safety in everyday practice. It provides opportunities for our clinical teams to learn and grow together, to benefit from each other's sub-specialty expertise and experience and, ultimately, to join their forces for a better clinical outcome.

Burnout in Radiology – What do Studies Say?

Medical imaging represents the gateway into the healthcare system and the decision making for patient management. This has resulted in significant increase in the demand for

diagnostic imaging in the last years. Radiologists are requested to cope with this high demand by increasing the number of reports and their working hours. In addition, the shortage of radiologists in Europe results in longer reporting times and higher volumes, while at the same time the demand from patients and referrals for sub-specialty expertise in radiology increases with a focus on more detailed and precise reports.

Discrepancy in diagnostic imaging reporting is considered common. Different studies in radiology show that there is an estimated day-to-day rate of diagnostic discrepancies of 3–5% of studies reported. An example from radiology literature (Abujudeh et al. 2010) is a second readings analysis of abdominal and pelvic computer tomography (CT) examinations by experienced abdominal imaging radiologists in which radiologists disagreed with each other more than 30% of the time and disagreed with themselves more than 25% of the time when they were asked to re-interpret their previous reports.



The causes of different discrepancies in diagnostic imaging are multiple, as we can see from **Table 1**:

Referral physician	· Incomplete clinical information · Inappropriate expectations of the capabilities of a radiological technique · Limited in-depth knowledge of the patients
Technical factors	· Imaging protocol used, inappropriate contrast or patient not respecting the procedure · Staff shortages and/or excess workload, staff inexperience, inadequate equipment, less than optimal reporting equipment
Communication failings	· Poorly written/incoherent report · Interpretation report · Voice recognition
Reporting	· Interruptions · Visual and/or mental fatigue · Inattentional blindness

Table 1: Short list of causes of discrepancies in diagnostic imaging. Source: Brady 2017

Organised and continuous peer review of reported examinations has been advocated as a quality assurance tool to identify and minimise discrepancies, improve reporting quality and promote clinical excellence. For a safe and effective service, it is essential that discrepancies considered to be clinically significant are reviewed, acted upon and learned from in order to improve clinical services quality.

How is Affidea Always Ensuring High Quality Standards and Diagnostic Accuracy?

As the leading European provider for advanced diagnostic imaging, looking for proven clinical quality improvement tools, Affidea has implemented a peer review system of the reported examinations.

Peer review is defined as the anonymised and blinded process by which a reviewing radiologist assesses a scan and compares his interpretation of the images to a report previously written and authorised by the primary radiologist. All discrepancies identified are discussed during discrepancy meetings and targeted actions are agreed to improve the results. These actions include educational plans, training in focused subspecialties in radiology, training in pattern recognition and repetition, and improvement of reporting conditions.

Peer review allows the assessment, mitigation and prevention of errors that improves and maintains quality and diagnostic accuracy of the radiology report. Moreover, peer review improves patient confidence and trust to the clinical services provided and also ensures accountability of radiologists.

Currently, four Affidea countries are systematically using peer review for CT and MRI report quality improvement and another two countries will launch the same before year-end. In 2022, all Affidea countries performing diagnostic imaging examinations will have an organised peer review process in place, as part of our everyday activities. The results are followed up monthly and demonstrate a significantly lower percentage of discrepancies in the radiology report, in comparison with different studies. The key factor is to continuously screen and improve the clinical services provided across all diagnostic imaging centres in 15 countries, giving radiologists the possibility to support the medical outcome in a safe and effective way.

Next steps would be to include more modalities in the peer review process, such as mammography and x-rays, but also nuclear medicine reports and cancer therapy processes to enlarge the area of clinical services that are cross-checked. At the same time, at Affidea we are planning to install a Peer Review software, which would select the tests to be performed in a fully automated way. This will make the entire quality control system even easier and more automatic. Possible use of AI solutions (e.g. for the orchestration of the exams selection or image quality assessment) is continuously monitored with the scope to support the extension of the peer-review process and to accelerate the related activities.

At Affidea, patient safety and continuous improvement in the quality of our clinical services are part of our DNA. Peer review is proven effective to ensure that our quality goals are reached, with patient care at the core of everything we do. ■

REFERENCES

Abujudeh HH, Boland GW, Kaewlai R et al. (2010) Abdominal and pelvic computed tomography (CT) interpretation: discrepancy rates among experienced radiologists. Eur Radiol, 20(8):1952–1957.

Brady AP (2017) Error and discrepancy in radiology: inevitable or avoidable? Insights Imaging, 8:171–182

Why is the Pharmaceutical Industry Not Developing New Antibiotics?

Author: **Samna Ghani I Managing Editor I ICU Management & Practice I Senior Editor I HealthManagement.org I** Cyprus

An overview of antibiotic resistance, causative factors, reasons for the lack of research and drug development in this area and potential solutions.

Key Points

- Antibiotic resistance is one of the biggest threats to global health.
- The primary culprit of fuelling antibiotic resistance is the misuse and overuse of existing antibiotic drugs.
- Poor infection prevention and control is another key driver of antibiotic resistance.
- There are many low-income countries where antibiotics are unregulated and available over the counter without a prescription.
- The last original class of antibiotics was discovered in the 1980s, but since then, no new or advanced antimicrobial agents have been introduced by pharmaceutical companies.
- High costs, a long regulatory process and minimal revenues are some reasons why pharmaceutical companies have exited out of this particular area of drug development.

According to the World Health Organization (WHO), antibiotic resistance is one of the biggest threats to global health (WHO 2020). Antibiotic resistance is increasing to dangerously high levels across the globe and is threatening the ability of clinicians to treat common infectious diseases. As this resistance continues to grow, the ability to treat infections such as pneumonia, tuberculosis, food-borne diseases and others is becoming more difficult. Antibiotics are essential drugs for many common medical problems - from organ transplants to food poisoning. Resistant bacteria kill nearly 700,000 people every year. If the problem of antibiotic resistance continues to remain unchecked, the global death toll from this could increase to 10 million a year by 2050 (Jinks 2017).

Why Does Antibiotic Resistance Occur?

The biggest culprit of fuelling antibiotic resistance is the misuse and overuse of existing antibiotic drugs. According to Public Health England, nearly a fifth of antibiotic prescriptions are unnecessary (Jinks 2017). Moreover, antibiotics are often incorrectly prescribed, which promotes resistant bacteria. According to studies, the choice of antibiotic drug and/or the duration of antibiotic therapy is incorrect in nearly 30 to 50% of cases (CDC 2013; Luyt et al. 2014). In intensive care units, in particular, 30 to 60% of antibiotics prescribed are deemed unnecessary, inappropriate or suboptimal (Luyt et al. 2014). The use of antibiotics is also common in agriculture. 80% of antibiotics sold in the U.S. are used in animals to prevent infection. These antibiotics, once consumed by livestock, are then ingested by humans. This transfer from farm animals to humans through food supply is also a contributor to the development of resistant bacteria (Bartlett et al. 2013).

Epidemiological studies demonstrate a relationship between antibiotic consumption and antibiotic resistance. However, despite repeated warnings, antibiotics continue to be overused and overprescribed worldwide (Ventola 2015). Poor infection prevention and control is another key driver of antibiotic resistance. In addition, there are many low-income countries where antibiotics are unregulated, and people can get them over the counter without a prescription. This makes antibiotics easily accessible and also promotes overuse which, in turn, contributes to the development of resistant bacteria (Ventola 2015).

Why the Lag in Antibiotic Drug Development?

The last original class of antibiotic was discovered in the 1980s, but since then, no new or advanced antimicrobial agents have been introduced by pharmaceutical companies (Plackett 2020). According to a report by the WHO, big pharma has walked away from investment in new antibiotics with the clinical pipeline insufficient to tackle the problem of antibiotic resistance. The report highlights that only small and medium-sized enterprises are making some effort, but most large pharmaceutical companies have exited from this area. Only eight new antibacterial agents have been approved since 2017, and most of them have demonstrated limited clinical benefits (WHO 2019).

One of the biggest reasons the pharma industry is not interested in antibiotic drug development is that it is an extremely costly venture. According to estimates, the cost of developing an antibiotic is around $1.5 billion (Towse et al. 2017), but the revenue generated from antibiotic sales is around $46 million per year. For pharma companies, this minute return does not justify the amount of time, money and effort required to develop new antibiotics. Investing in more lucrative areas such as cancer treatments may be more feasible for the industry. Similarly, investing in drugs that target chronic diseases (such as cardiovascular disease, musculoskeletal conditions etc.) is more profitable for pharmaceutical companies because these are typically prescribed for the long-term, whereas a typical course of antibiotic therapy lasts from 7-14 days (Plackett 2020).

Potential Solutions

As far as the antibiotic drug development process is concerned, the costliest phase for pharmaceutical companies is the preclinical stage. At this stage, there is no guarantee that the molecule will demonstrate the desired efficacy and safety. Nearly 45% of costs are associated with the preclinical phase, and if the drug being developed does not pan out, it is a loss for the industry. This may be one reason why the industry is not enthusiastic about antibiotic development. If the development costs could be reduced, the motivation for more research and development in this area is likely to increase. Some researchers recommend the use of more sophisticated approaches in the early stage of drug development, which would also involve the use of big data analysis and artificial intelligence (AI) to predict which molecules are likely to have the desired antibiotic properties to make it through the final stages of efficacy, safety and approval (Stokes et al. 2020).

Also, keeping in mind the urgency of this issue, governments and regulatory bodies may have to become involved to promote investment of time, effort and money for antibiotic drug development. Some healthcare providers and drug companies have switched to a subscription-based model where companies receive an up-front payment during the early stages of development as an incentive to start the research process. This is being tried in the U.K., where the government will award contracts to companies who will receive money in installments during the early stages of R&D. This strategy could be effective as it would help break down the restrictive barriers that companies have with respect to the investment they need during the preclinical stage (Plackett 2020).

Resistant bacteria kill nearly 700,000 people every year, and if the problem of antibiotic resistance continues to remain unchecked, the global death toll from this could increase to 10 million a year by 2050

Conclusion

At this stage, the progression rate of research and development of antibiotics remains bleak. At the rate the industry is going, the WHO estimates that only around 11 new antibiotic approvals could take place over the next four to five years (WHO 2019). However, most of these drugs are modifications of existing classes of antibiotics and may not be that effective against the more critical and the more resistant bacteria. The high cost at the early stage of research, the funding required for conducting Phase 2 and Phase 3 clinical trials, and the minimal revenues continue to be discouraging factors for the pharmaceutical industry. Governments and other stakeholders will have to step up to address the problem of antibiotic resistance. They need to understand the importance and value of antibiotic drugs in healthcare and the urgent need to push the antibiotic drug pipeline in the right direction.

Conflict of Interest

None. ■

REFERENCES

Bartlett JG, Gilbert DN, Spellberg B (2013) Seven ways to preserve the miracle of antibiotics. Clin Infect Dis, 56(10):1445–1450.

Centers for Disease Control and Prevention (2021) Antibiotic prescribing and use. Available from https://www.cdc.gov/antibiotic-use/index.html

Jinks T (2017) Why is it so difficult to discover new antibiotics? Available from https://www.bbc.com/news/health-41693229

Luyt CE, Brechot N, Trouillet JL, Chastre J (2014) Antibiotic stewardship in the intensive care unit. Crit Care, 18(5):480.

Plackett B (2020) Why big pharma has abandoned antibiotics. Nature, 586:S50-S52.

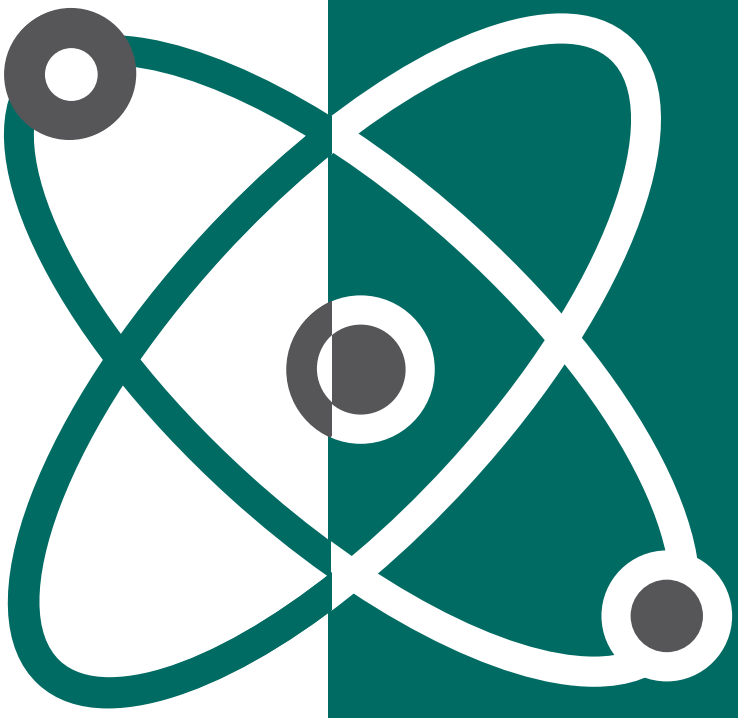
Stokes JM, Yang K, Swanson K et al. (2020) A Deep Learning Approach to Antibiotic Discovery. Cell, 180(4):688-702.e13.

Towse A, Hoyle CK, Goodall J et al. (2017) Time for a change in how new antibiotics are reimbursed: Development of an insurance framework for funding new antibiotics based on a policy of risk mitigation. Health Policy, 121(10):1025-1030.

Ventola CL (2015) The antibiotic resistance crisis: part 1: causes and threats. P.T. 40(4):277-283

WHO (2020) Antibiotic Resistance. Key Facts. Available from https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance.

WHO (2019) 2019 Antibacterial agents in clinical development: An analysis of the antibacterial clinical development pipeline. Available from https://apps.who.int/iris/bitstream/handle/10665/330420/9789240000193-eng.pdf



WINNING PRACTICES

"There is no comprehensive health data governance at the EU level, and very few member states could be said to have one at the national level" *page 474*

The EU Health Data Centre: A New Total Virtual Organisation

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The COVID-19 pandemic revealed that the EU has no clear health data architecture regarding health data, its availability and comparability. There is a lack of harmonisation and an absence of an EU-level centre for health data analysis and use to support a better response to public health crises. Through extensive desk review, interviews with key actors and enquiry into experiences from outside the EU/EEA area, a recent study for the Panel for the Future of Science and Technology (STOA) highlights that the EU must have the capacity to use data more effectively and make data-supported public health policy proposals and inform political decisions.

Key Points

- The COVID-19 pandemic has made it clear all data may be needed to prevent, perceive, detect, alert, respond and recover.
- Centralised governance structure in a crisis must have the capacity to use data more effectively.
- The pandemic has shown that the EU needs a new weapon - a European Health Data Agency – to better prepare, prevent and respond to similar or worst crises and to welcome the possibility of a new breed of EU Agencies, born out of virtuality and "materialised" in a totally virtual format as a Total Virtual Organisation.
- Four types of public health data were considered:. Data on Communicable Diseases (DCD); Data on Non-Communicable Diseases (DNCD); Data about the Health System (DHS); and Data with a public health relevance (DPHR).

The Issue at Hand

The COVID-19 pandemic brought about such significant societal impacts in the European Union (EU) that only time and distance will allow us to grasp their full extent (European Commission Communication 2020). The STOA study "EU health data centre and a common data strategy for public health" (Martins 2021) is a "humble attempt to take a picture of an incredibly fast-moving object, the size of the Union, and impacting each and every one of its millions of inhabitants in unique, unforeseen, radical and life-changing (for some, unfortunately, life-taking) ways". This paper aims to present a summary of this study, advance a personal opinion about the options presented and suggest an innovative way forward for the establishment of a new type of EU Agency, akin to the new times and future needs in health data exploration. This is ever more pressing when "early lessons learnt with COVID-19 have shown that the current system has not ensured an optimal response at EU level to the COVID-19 pandemic" (European Commission Proposal 2020).

Alemanno (2020) advances a set of provisional explanations for what he calls "the global suboptimal response to an essentially foreseeable outbreak such as a pandemic". He suggests one explanation is "the inability to mobilise the unprecedented wealth of data collected today to counter the virus due to the absence of a data governance and data-sharing culture as well as public–private infrastructure". This refers to data relevance in public health. In its official position, the European Parliament, in its resolution of 10 July 2020 on the EU's public

health strategy post-COVID-19 (Parliament 2020), called for a strong push on a European Health Union, where data is central to this construct.

Despite the EU Member States (MS) sharing of a set of health system common values, reiterated by the 2006 European Council conclusions, the best word that characterises the EU response since the first day is: ***Heterogeneity***. Regarding data, its availability and comparability, the COVID-19 pandemic revealed that ***the EU has no clear health data architecture*** and that even simple statistics on elements like intensive care beds, the number of active cases under surveillance or availability of professionals were limited by national and even regional idiosyncratic differing interpretations. The lack of harmonisation in these practices is also a result of the lack of national comparable data and the absence of multilateral collaboration on data analytics. The problems with differing criteria for recording, documenting and using populational health data have long been identified by a series of projects funded by the European Commission (EC) and collaboration networks.

On 11 November 2020, the EC presented a pack of proposals under the 'European Health Union' umbrella to help address the EU response to public health crises. Some steps towards a new "sort of agency", called Health Emergency and Response Agency (HERA), have materialised slowly. Now, November 2021, one year later, and on the verge of another wave of pandemic uprise it is time to ask the question. European Health (data) Union: Quo vadis?

There is no comprehensive health data governance at the EU level, and very few MS could be said to have one at the national level as well. This impacts severely any holistic thinking of data usage and information systems, but this is an opportunity for ground-breaking policy. In today's world, with learnings from the COVID-19 pandemic and foresight into larger, possibly hybrid, cross-border threats, ***all data may be needed to prevent, perceive, detect, alert, respond and recover***. Even with such a holistic and encompassing view of data usage, MS freedom and responsibility for organising their health systems may not be disturbed as much as needed for public health safety, a responsibility which they also have, and that, increasingly, can only be met in multilateral work, even in inter-critical periods.

A "truly centralised" governance structure for dealing with these types of crises is needed. Not just on a structure for "governance of data and how it helps emergency coordination and response" but the "governance of the overall EU-level response". Without the latter, the former is more difficult to achieve. A centralised governance structure in a crisis must have the capacity to use data very effectively and make data-supported public health policy proposals and inform political decisions.

Four types of public health data were considered: 1. Data on Communicable Diseases (DCD); 2. Data on Non-Communicable Diseases (DNCD); 3. Data about the Health System (DHS); 4. Data with a public health relevance (DPHR), which means non-health data with the potential to be relevant for public health functions.

There is no well-defined or ill-defined common European strategy on how to collect data. Simply **there is NO strategy which could be considered "common" on data collection**.

The COVID-19 pandemic revealed that the EU has no clear health data architecture

As the EU discusses the recently proposed 'Data Governance Act' (European Commission Proposal on European Data Governance 2020) and has a scheduled legal discussion on the European Health Data Space, it is worth mentioning that both can be legal umbrellas for a 'Health (Public Health) Data Governance Act" only if there is a wider understanding of its complexities and necessities as subsequent legislation. An alternative policy option is to have a stand-alone, albeit articulated, legal and organisational stream dedicated only to "health data" understood in a broad sense and not in a narrow classical public health perspective. A set of policy solutions to the present absence of a common European strategy on data collection was offered **as four preliminary options were formulated in advance**.

Establishing a European Health Data Agency – A Stand-Alone Agency

After a careful appreciation of the EU regulatory framework in the fields of data collection/exchange, testing/reporting methodologies and public health and the law of "cross-border" health threats and the analysis of the adequacy of current EU institutional structures **four preliminary options** were suggested for the institutional "home" of an **EU Health Data Centre**. The centre can only fulfil its mandate if it **has the power and competency to influence MS public-health-relevant data ecosystems and institutionally link with their national actors**. Such a response structure needs to be a continuous activity, capable of driving the EU health data strategy and agenda, and capable of liaison with MS internal public health data structures and authorities to ***establish functional public-health-relevant data pipelines*** by building technical connectivity and upskilling the workforce in digital health and data science. The i**nstitutional structure can be located inside an agency or as a stand-alone agency,**

bearing a mix of regulatory agency and technical competence centre attributes.

A permanent central structure dealing with health data at EU level, particularly if it covers public health data understood in the broad sense ***will fill a severe actual governance gap***. However, to really have an impact on public health preparedness and betterment of populational health in the EU, such a structure should support multiple EU-level actors/agencies, and needs access and the capacity to process four large sets of data/health information from MS. To show how the structure would undertake its role and serve its mission during a crisis and in between crises, an illustrative set of main operational activities/services it would entertain were outlined.

The study also outlines the main tenets for an "European strategy on how to collect data for preventing, detecting and curing diseases". The legal mandate of the EU Health Data Centre should contain the provisions for "emergency-only" digital services, such as some advanced analytic solutions, definitely persons surveillance via digital and Artificial Intelligence (AI) powered tools, and the opening of digital therapeutics and digital interaction services direct to EU citizens. Explaining these services to each citizen should be guaranteed during and after emergency, and when they utilise AI.

Combining options studied regarding an EU Health Data Centre and a common European strategy to collect health data to help coordination and emergency response to a serious cross-border threat resulted in four main options ("do nothing" is not discussed) of which three are outlined and correspond to three organisational arrangements and two levels of strategy formalisation.

I favour option four - **Establishing a European Health Data Agency (EHDA)**. If one year ago that was dubious and debatable, now, in November 2021 that is "crystal clear". Such an agency's core mission would be to aggregate all existing capacities and digital health EC competencies, as well as public health indicator activities, include additional ones needed and serve the EC and its Agencies. Finally, act as the main governance agency on the European Data Space on behalf of the "health sector" more broadly, a key discussion as the EDS governance has not yet been finalised.

The actions of the EHDA on health data at the EU would be subject to the development of sustainable strategy under the mandate of **a health (public health) data governance act**. Such would have the virtue of stimulating a much needed European and societal debate about health data and healthcare outcomes in the Union. Finally, such a setting could create conditions for a future European Public Health Authority (EPHA), with full-fledged powers to be activated under certain conditions and in strict articulation with existing EU powers. In this case, a new agency – European Health Data Agency (EHDA) - is created. EHDA is created as a stand-alone agency, not just to use public-health-relevant data during a public health crisis, but to fundamentally collect, use and analyse the four main types of health data in crisis and inter-critical periods.

There is no comprehensive health data governance at the EU level, and very few member states could be said to have one at the national level

The Concept of Total Virtual Organisations (TVOs)

The idea that an EU agency must occupy a physical building often in one of the MS capitals, is disputed by many due to the fact that it constitutes a source of city income and reputation while providing sustainable attraction for highly differentiated professionals and fixation of EU-financial streams can also be disputed. The move of EMA was an example of such paradigm, but for a European Health Data Agency, to be launched as early as possible but always in 2023 or beyond, there are other possibilities.

There are organisations that bear no physical existence. Often private or non-for-profit organisations, in the humanitarian domain, the standardisation world, in the arts, scientific societies, or other international examples. Many multinational companies have experimented successfully with "digital academies", "data analytic centres of excellence" operated from staff residing in their homes under strict tele-leadership command and control scenarios.

These experiments constitute totally virtual organisational arrangements, parts of organisations, or indeed complete organisations. A virtual organisation is therefore an organisation that does not have, or will have, any physical headquarters, nor have "facilities" of its own, it does not have a "home" in the physical world. To be true to the spirit of total dematerialisation, a virtual organisation where there is never a moment where its members meet in the physical world could be considered a Total Virtual Organisation (TVO).

TVOs make sense when data is the core substance of work. Data is an intangible asset. EU law covers extensively how outsourced physical data centres – hosting mega computers, servers and all the necessary information technology (IT) – can be used lawfully and under strict cybersecurity EU rules.

How to Move and Start a New Type of EU Agency

The second more important resource for the success of a European Health Data Agency (EHDA) is human capital. The widest access to the best professionals, not just informatic professionals, but health informaticians, public health and other clinical specialist knowledge and many other societal health multidisciplinary knowledge workers. They are in abundance in the EU. Often, they are not willing to move into one "corner" of the EU space, often with complex family and work networks fundamental for their intellectual pedigree. These are not "common" officials we need, but highly skilled and advanced individuals who, by nature of their longstanding education and essential knowledge networks cannot be easily displaced or are willing to temporarily move. Bringing them together online, is possible, effective and is a lesson from the COVID pandemic.

How to start? Large consensus on the need of the EHDA is necessary and requires political initiative from the Council, but also from the European Parliament. A set of Member States can initiate the debate and explore the idea of a first-ever totally virtual EU Agency. Discussions in the European Parliament can be stimulated by the STOA study, led by interested MEPs, and amplified by the future legal debates on the European Commission proposals for new Regulations under the European Health Union pack and future coming European Health Data Space legislation. Discussions by clusters of member states in Council initiatives or as part of bilateral and multilateral policy initiatives could also be a way to start. Whatever is the way, we need to start sooner rather than later.

Conclusion

The future is a mystery, but worse and more likely hybrid threats (bio and cyber viruses or other) loom on the horizon. However, the EU can prepare for these by using health data much better. While doing that, it can add public health value in areas of public health smouldering crises that never come to be called emergencies (such as cancer or mental health). Policy in EU health digital integration may take large world-astonishing leaps, through courageous legislation and institutional reshaping to achieve real effective public health safety for its inhabitants

If the COVID-19 pandemic has shown us that we need a new EU weapon – a European Health Data Agency – to better prepare, prevent and respond to similar or worst crisis that isolated us and made us work virtually, it also inaugurates the possibility that such EHDA can be a new breed of EU Agencies, born out of virtuality and "materialised" in a totally virtual format as a Total Virtual Organisation.

Conflict of Interest

None. ■

REFERENCES

Alemanno A (2020) Taming COVID-19 by Regulation: An Opportunity for Self-Reflection. European Journal of Risk Regulation, 11(2):187–94. https://doi.org/10.1017/err.2020.43

European Commission. (2020) Communication From the Commission - Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats. COM 724 final. Available from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0724&from=EN

European Commission. (2020) Proposal for a regulation of the European parliament and of the council on serious cross-border threats to health and repealing Decision No 1082/2013/EU. COM 727 final. Available from proposal-regulation-cross-border-threats-health_en.pdf (europa.eu)

European Commission. (2020) Proposal for a regulation of the European parliament and of the council on European data governance (Data Governance Act). COM 767 final. Available from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020PC0767&from=EN

Martins H (2021) EU health data centre and a common data strategy for public health. Panel for the Future of Science and Technology (STOA). EuropeanParliament. Available from https://www.europarl.europa.eu/stoa/en/document/EPRS_STU(2021)690009

Parliament TE (2020) The EU's public health strategy post-COVID-19.

AI vs Human: The Use of Artificial Intelligence for Medical Analysis

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An overview of the role of Artificial Intelligence during the treatment process and implementation of AI algorithms to increase patient awareness and improve access to anonymised data.

Artificial intelligence has been pushing itself into the digital space of the medical industry for several years. Recently, however, this process has accelerated significantly. Newer and more effective diagnostic algorithms are emerging, but what is equally important is that their real use in medicine is increasing. More and more relatively simple, time-consuming tasks, so disliked by doctors, are being replaced by algorithms. Medical staff are beginning to notice that artificial intelligence is not there to replace doctors, but to help them in their work. This difference in perception and rejection of fears makes doctors understand the enormous advantages of artificial intelligence, however imperfect it may still be (Songhee et al. 2019).

Analysis of 720 Hours of Examination in Seconds

A great example of artificial intelligence algorithms supporting medical personnel can be any kind of long-term testing or screening. In both cases, it is necessary to analyse a lot of data. Comarch offers cardiac telemonitoring services, which analyse and detect silent atrial fibrillation in a 30-day ECG examination. This episodic disorder is very difficult or even impossible to detect with an ordinary 24-hour holter, since it occurs relatively rarely, without noticeable symptoms (Barbarossa et al. 2014). Performing such a long study would not be possible without AI algorithms. **Reviewing 720 hours of signals by a medic or technician would be a great effort, and that's just for one patient**. Artificial intelligence algorithms first filter out unnecessary fragments of the signal (the correct signal or interference). After all, the doctor does not have to look at these. **The doctor is presented with only parts in which the AI has noticed a high degree of probability of disorders occurring**. The browser gives you the opportunity to quickly mark the selected fragments as true or false detection, and after completing the entire 30-day examination, these data are presented in a friendly report for the patient. This is a perfect example of how **AI improves medical analysis**. Without automation, such a study would be almost impossible or extremely expensive, which would translate into its limited availability.

AI in Imaging Diagnostics

Another example can be all kinds of algorithms to support diagnosis in imaging tests. Quick identification of suspicious fragments allows a doctor to save invaluable time, make decisions and implement treatment. Detection of cancer lesions from MRI, CT or mammography images are just a few examples of the use of artificial intelligence in the fight against cancers (Oren et al. 2020) and other diseases. Recently, however, the global pandemic has expanded the scope of AI use in imaging research. Algorithms, based on x-rays, CT or MRI of the chest, are able to very quickly assess the degree of lung damage or carry out triage of patients (DeGrave et al. 2021).

Application Instead of a Binder With Medical Records

Equally important from the point of view of fast and accurate diagnostics is the management of your own medical records. Having full documentation always where you need it allows you to share selected elements of it with doctors. However, it is very often that patients get documents in paper form, as a result of which they come to the doctor with a large binder. This is where the Comarch MojeZdrowie24 application comes in handy, allowing, for instance, storage and management of results of medical checks. We store documents in the form of

photos, and adding more files is extremely simple. **But what if a great many of these documents are collected?** This is where AI algorithms that can determine the type of document and indicate the keywords that will come in handy. This makes searching our digital medical records extremely easy.

course, technology will not completely replace this important stage of drug development, but it will allow you to better prepare for it and can reduce the costs and time spent on recruiting a control group.

These are just a few examples of how artificial intelligence supports the treatment process - from the creation of drugs

Algorithms, based on x-rays, CT or MRI of the chest, are able to very quickly assess the degree of lung damage or carry out triage of patients

Digital Twins Instead of a Control Group

An extremely interesting direction of development of AI in medicine is the creation of **"digital twins"**, used as a control group at the stage of clinical trials or to predict the progression of a given disease (for example, Alzheimer's) (Kesari 2021). These are models that describe the current and future state of health of patients, such as predicted reactions to a drug or the progression of a disease (Fisher 2019). This solution would significantly speed up and reduce the cost of human testing during the implementation of new drugs. Of

to diagnosis, management of medical records, and supervision of the treatment of patients. From year to year, more and more such systems appear. However, the key problem when creating these solutions is data. Currently, legal regulations do not allow easy access to medical data. However, I believe that the benefits of implementing AI algorithms in medicine will increase patient awareness and allow easier access to anonymised data, which as a result will allow more dynamic growth of AI-assisted services. ■

REFERENCES

Barbarossa A, Guerra F, Capucci A (2014) Silent Atrial Fibrillation: A Critical Review. J Atr Fibrillation, 7(3):1138.

DeGrave AJ, Janizek JD, Lee SI (2021) AI for radiographic COVID-19 detection selects shortcuts over signal. Nat Mach Intell 3, 610–619

Fisher C (2019) Creating Digital Twin Controls for Alzheimer's Disease Using Machine Learning. Unlearn.AI.Inc.

Kesari G (2021) Meet Your Digital Twin: The Coming Revolution In Drug Develoment. Forbes. Available from https://www.forbes.com/sites/ganeskesari/2021/09/29meet-your-digital-twin-the-coming-revolution-in-drug-development/?sh=390eb29745fb

Oh S, Kim JH, Choi SW et al. (2019) Physician Confidence in Artificial Intelligence: An Online Mobile Survey. J Med Internet Res, 21(3):e12422.

Oren O, Gersh B, Bhatt D (2020) Artificial intelligence in medical imaging: switching from radiographic pathological data to clinically meaningful endpoints. The Lancet Digital Health. 2. e486-e488.

Looking for Lessons to Support ICS Digital Plans for Integrated Care

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Plans for digitally-enabled integrated care can look great on paper, but what needs to happen for them to succeed on the ground? As policy accelerates in the UK, Dr Meetali Kakad, chief medical officer at Dignio, takes a snapshot look at lessons from around the world.

Key Points

- Emerging digital plans in integrated care systems should actively focus on patients.
- Digital initiatives should be patient-centric, share decision-making, and account for professionals' wishes, daily practices, and values.
- Key features of successful programmes include targeting resources to highly vulnerable people, a shared care record for data transparency and communication, and flexibility in care.

I recently spoke to a kidney transplant patient who embodied the need for successfully integrated care systems. He said that he had been admitted to the hospital twelve times in a matter of months two years earlier.

His complex condition, which included diabetes, limited kidney function, and the effects of immunosuppressants prescribed to prevent transplant rejection, had at the time led to several infections and sepsis.

Recognising the frequency of his hospital admissions, district nurses decided to place him on a remote monitoring programme. A care management plan was concurrently devised in collaboration with the patient and a multidisciplinary team that included his nephrologist at the local hospital.

As part of the treatment plan, the nephrologist insisted that if any likelihood of infection was detected, the patient should go straight to the hospital, where he would receive specialist care immediately – rather than the typical route of initially seeing a general practitioner.

This patient was 'right as rain' one day and doing very ill on the next. For him, reporting a runny nose meant a high likelihood of becoming unwell on the following day.

Being remotely home-monitored in a programme that drew on connected devices and an easy-to-use app capable of alerting his care team at the first sign of deterioration made a significant impact. Being able to detect risks early allowed appropriate action relevant for that individual to be taken. And in the past twelve months, the patient hasn't had any unexpected hospital admissions.

One Anecdote, Wider Meaning

This is only a single anecdote, but it explains why patients must be at the core of emerging digital plans in integrated care systems. Technology can support personalised and effective care for an individual, but only if that individual's needs are properly considered by different parts of the health and care system.

The patient's story ensues from an integrated care project, supported by the Norwegian Directorate of Health, as part of a broader programme assessing the use of remote care. The programme, which Dignio supported, has helped reduce hospital admissions for patients by a third, with an even larger impact on lengths of stay and emergency admissions.

Lessons From Around the World

It is just one programme of many worldwide that integrated

care systems in the UK might look to for lessons as they develop and implement plans for digitally-enabled integrated care.

In England, an abundance of strategies has recently emerged from NHSX, a tech unit designed to help integrated care systems address digital priorities. These include a new data strategy for health and care, known as 'Data Saves Lives', a digital clinical safety strategy, and a new framework targeted at integrated care system leaders, outlining 'What Good Looks Like' in digital transformation (NHS Choices 2021a; NHS Choices 2021b; NHS Choices 2021c).

Seeing such a convergence of ideas is a positive development. But experience has also shown that 'what good looks like' on the ground might differ from the documented policy.

Lessons of Caution

Lessons of caution might be drawn, for example, from a large-scale project in Odense, a Danish municipality, which itself drew on an integrated care pilot programme in North West London. A Danish study (Buch et al. 2018) noted that the "ill-fated" programme "failed at the clinical level" during implementation, despite "an ambitious setup, ample financing, a shared governance structure and a well-functioning project organisation". Researchers from the Danish Institute for Social Science Research cited primary explanations as "an overly optimistic timeframe and a failure to take professionals' wishes, daily practices, and values into account".

Sweden, too, offers insights into where results might differ from expectations. Researchers at the Karolinska Institute and Sweden's Aging Research Centre (Doheny et al. 2020) examined mixed results in implementing an integrated care system in Stockholm's Norrtälje municipality. The paper cited "a modest decrease in the trend of the rate of ED visits". The system was arguably perfectly planned. But lessons could be drawn around sufficiently anchoring the initiative in the local area with the right people.

Reasons for Optimism

Despite the challenges, there are many programmes throughout the world delivering significant success in integrated care.

Germany offers integrated care system leaders a glowing example. Gesundes Kinzigtal, a partnership between clinicians and the data analytics company, OptiMedis AG, has done many things well – from initial design and using data to help clinicians identify high cost, high need patients through population health risk stratification.

The partnership has been very patient-centric, with workaround audit and feedback strategies and patient activation. The organisation invested in individual treatment plans, goal setting between doctors and patients, and shared decision making. Care planning has been based on decision support and self-care, with a strong focus on patient coaching and providing the proper care at the right time. A paper in Handbook Integrated Care (Groene and Hildebrandt 2017) records improvements in multiple areas.

Integrated care systems must bring stakeholders together and get buy-in from leadership in multiple organisations

Other impressive examples include Canada's PRISMA programme in French Quebec. Réjean Hébert, a professor at Université de Montréal and former health minister, has published findings (Hébert 2021) on the initiative, which utilises computerised care plans in the care of older and frail individuals. This initiative is a strong example of joined-up working across multi-disciplinary teams, underpinned by shared decision making and effective pathways.

Successful initiatives from around the world are, in fact, too numerous in number to mention. Lessons can certainly be drawn from both sides of the Atlantic. The UK itself already has a large number of initiatives from which integrated care systems could learn.

One initiative, recently becoming better known, has taken place in Stockport. A collaboration between out-of-hospital provider Mastercall Healthcare and Stockport Metropolitan Borough Council and Dignio has seen a significant reduction in hospital admissions for at-risk patients whilst supporting people to feel safe and cared for at home.

The council and Mastercall Healthcare invested in a remote care platform that allows patients to be monitored remotely, with clinicians alerted to intervene early when necessary. A 44% hospital admission avoidance has been recorded for patients, and distress for vulnerable people for whom hospital visits can be traumatic has been reduced.

Common Themes for Success

The Stockport initiative has presented individual treatment plans, goal setting, and shared decision-making between patients and professionals. These are common themes consistently present in many of the above examples and other successful integrated care system initiatives throughout

the world.

Being able to target resources to highly vulnerable people is also increasingly important. If one can build care around the needs of those groups, then ambulance call-outs and admissions can be avoided, as can the knock-on effect of costly care and treatment. Having an effective, shared care record here can be vital to enabling the transparency of data required to build pathways around the person, rather than building pathways around vertical silos or individual illnesses. Working with one diagnosis at a time can be very laborious for both patients and providers. Digital plans and technology deployed must allow people to work around the individual flexibly.

Technology, designed and tested to meet user needs, is essential to providing successful integrated care. But often, the biggest challenge is the human factor. Integrated care systems must bring stakeholders together and get buy-in from leadership in multiple organisations. A multi-agency approach may even need to encompass areas like housing. Setting up structures that allow organisations that haven't worked together before to draw on technology is challenging and should not be under-estimated. Political and governmental will must also have equal longevity.

But what does success fundamentally constitute? A focus on patient-centricity is critical. Regarding the opening patient example, professionals from different organisations in Norway focussed on the needs of the individual in front of them. They were less concerned with referral routes and more concerned about responsively using data and technology to deliver the proper care. Focussing on 'what good looks like', digital integrated care initiatives must ask this question of the individual patients they are there to serve.

Conflict of Interest

Dr Meetali Kakad is the Chief Medical Officer at Dignio. ■

REFERENCES

Buch MS, Kjellberg J, Holm-Petersen C (2018) Implementing Integrated Care - Lessons from the Odense Integrated Care Trial. Int J Integr Care, 18(4), 6.

Doheny M et al. (2020) Impact of integrated care on trends in the rate of emergency department visits among older persons in Stockholm County: an interrupted time series analysis. BMJ Open, 10(6), e036182.

Groene O and Hildebrandt H (2017) Germany: Evolution and Scaling Up of the Population-Based Integrated Health Care System "Healthy Kinzigtal", in Amelung, V, Stein, V, Goodwin, N, Balicer, R, Nolte, E & Suter, E (eds), Handbook Integrated Care. Cham: Springer International Publishing, 511-524.

Hébert R (2021) Canada: Application of a Coordinated-Type Integration Model for Vulnerable Older People in Québec: The PRISMA Project, in Amelung, V, Stein, V, Suter, E, Goodwin, N, Nolte, E & Balicer, R (eds), Handbook Integrated Care, 2nd Edition, Springer International Publishing, 1075-1087.

NHS Choices (2021) Data Saves Lives, Available from: www.nhsx.nhs.uk/key-tools-and-info/data-saves-lives

NHS Choices (2021) Digital Clinical Safety Strategy, Available from: www.nhsx.nhs.uk/key-tools-and-info/digital-clinical-safety-strategy

NHS Choices (2021) What Good Looks like Framework, Available from: www.nhsx.nhs.uk/digitise-connect-transform/what-good-looks-like/what-good-looks-like-publication

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