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# Smart Diagnostics

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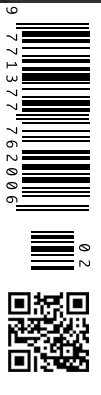
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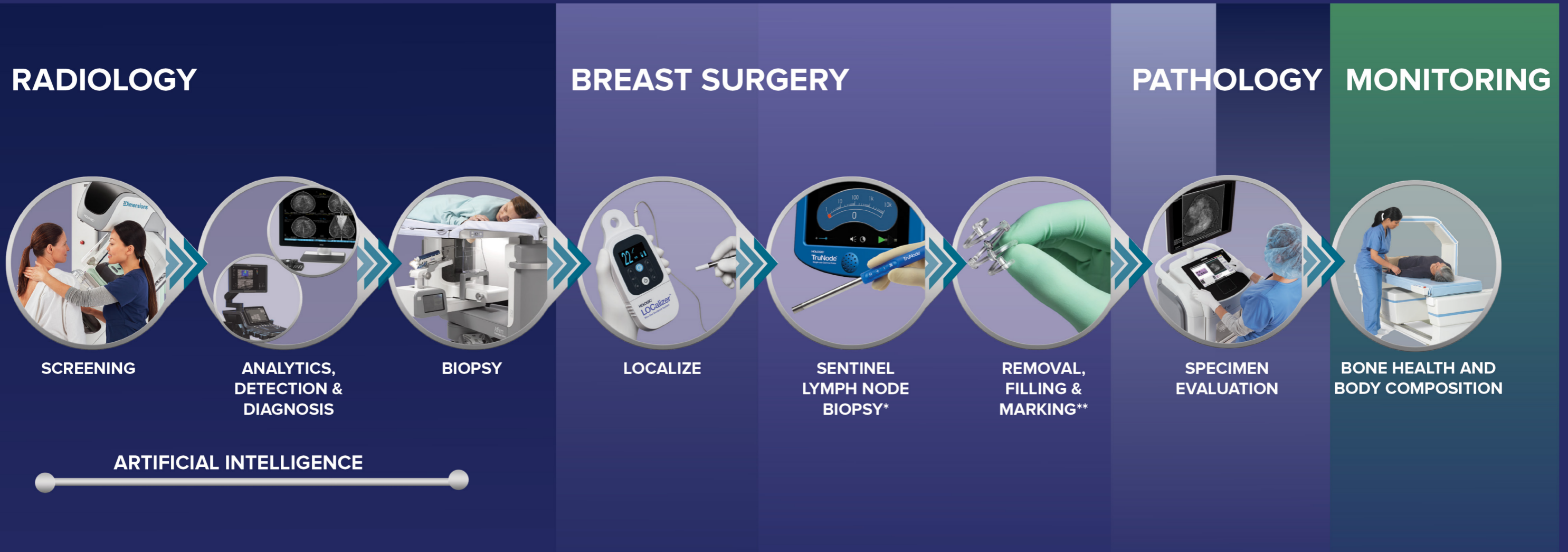
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# Editorial



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## Smart Diagnostics

Diagnostics in healthcare has always been an area that has been downplayed. That is probably why inaccurate and/or delayed diagnosis is something that has persisted in this field for decades. It is a systemic problem that continues to have an impact on patient treatment and outcomes.

The solution could potentially lie in smart diagnostics and on devices that could monitor patient health at all times and could help healthcare providers prevent, diagnose and treat patients efficiently and accurately.

We've already seen the use of smart and continuous monitoring in the field of cardiology where pacemakers and other implantables transmit information automatically and allow doctors to monitor and treat patients in case of a crisis. We have also seen an increase in the use of wearables that can help track individual health.

In this issue, our contributors talk about the application of **Smart Diagnostics** and the role advanced diagnostic approaches can play in preventing disease, monitoring patients and treating complex conditions.

Abeer Alzubaidi, Jonathan Tepper and Ahmad Lotfi discuss a deep feature learning model designed to discover biomarkers that are associated with cancer. Anna Ferrari, Sofia Vallecorsa and Alberto Di Meglio discuss the potential of wearable devices and artificial intelligence for improved diagnosis, management and treatment.

Gerard Castro and Suzanne Schrandt explore the use of technology and how it can drive diagnostic quality and improve the connection between clinicians and patients. Stephen Baker talks about the impact of Artificial Intelligence in breast imaging, and Jonathan Christensen discusses the current trends and developments in medical imaging technology.

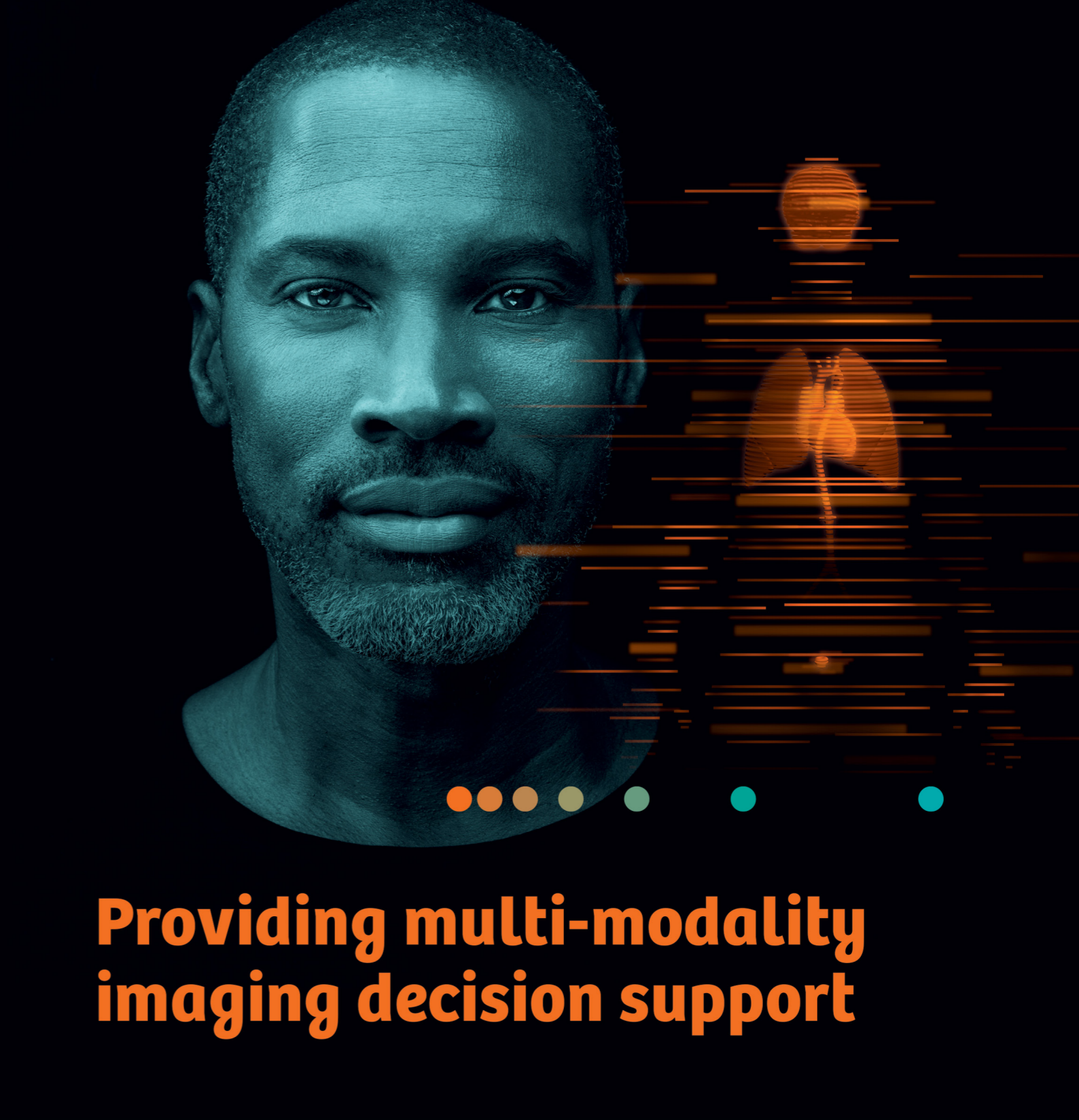
João Bocas highlights the importance of wearables, especially during an infectious disease outbreak such as COVID-19, while Alan Kramer, Dylan Bieber and Theresa Rohr-Kirchgraber discuss the influence of biotin supplementation on laboratory testing and the underdiagnosis of cardiovascular disease among women.

In Management Matters, Sherry Wang, Lily Wang and Jonathan Revels talk about junior faculty support and why it matters. Anna von Eiff, Wilfried von Eiff and Mohamed Ghanem discuss the concept of a Magnet Hospital and how this approach can direct care activities in an evidence-based manner. Erin Birch talks about personalised healthcare and how the NHS could become a customer-focused organisation.

The future of healthcare must focus on intercepting diseases at an early stage and preventing them altogether. But this can only be achieved if diagnostic tools become more advanced so that diagnosis can be improved and diagnostic errors can be reduced. The healthcare industry has always focused on discovering new drug treatments, but it needs to invest time and money on researching and developing smart diagnostics. A one-size-fits-all approach no longer works; the healthcare industry needs fresh ideas and solutions to improve diagnosis and patient care.

We hope this journal will provide you with valuable information. As always, we welcome your news and views.

Happy Reading!



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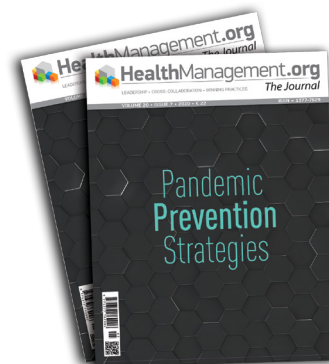
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## Have your say. Engage!



Recent advances in technology have led to a major shift in prevention, diagnosis and treatment. A one-size-fits-all approach is no longer feasible and we are moving fast towards a personalised patient pathway. Genomics, preventive lab tests and patient-centred care strategies have created new dynamics. Artificial Intelligence and Machine Learning are having an impact as well. With all these changes, how fast will we see progress in health-care? What fresh ideas and solutions are changing the game? What changes and smart diagnostic approaches do healthcare systems need to adopt to prevent diseases, diagnose patients accurately and treat them more effectively? This is what we explore in this issue.

To contribute, contact us on [Interested@HealthManagement.org](mailto:Interested@HealthManagement.org)

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# Junior Faculty Support: How To Do It and Why It Matters

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An overview of the themes of support from the perspective of junior faculty- the sequence of required processes, the breakdown of these processes and actionable courses that should be taken, both individual and/or institution-based.





## Key Points

- Junior faculty should be assigned a mentor prior to their arrival at an institution.
- Trust and confidentiality is the foundation of a mentor-mentee relationship.
- The availability of institutional resources should be concordant with the institutional expectations of the junior faculty.
- The best mentoring programme can falter under a toxic work culture.
- An institution can benefit greatly from the success of their junior faculties.
- Engaging junior faculty members early on is essential to ensuring their retention and institutional longevity.

Support of junior faculty is an essential catalyst for professional development in the setting of academia. The demand on junior faculty has increased over the years with increase in clinical workload, increase in burnout, inappropriate mentoring/sponsoring and inadequate protected time for research which is important to fulfil promotion criteria (Chetlen et al. 2019; Shaheen & Sandler 2018). Support for junior faculty can be divided into individual based - through mentors and sponsors, and institution-based and it should be emphasised that the success of all faculty is dependent on both types of support.

An institution can benefit greatly from the success of their junior faculties which makes this endeavour a true symbiotic relationship between junior faculty (mentee), mentor and their institution with success of an academic centre has been shown to be related to the degree to which junior faculty

are recruited, nurtured and promoted (Chapman & Guay-Woodford 2008).

This paper explores the themes of support from the perspective of junior faculty- the sequence of required processes, the breakdown of these processes and actionable courses that should be taken, both individual and/or institution-based.

### Initial Assessment

Junior faculty should be assigned a mentor prior to their arrival at an institution and a date and time should be set for an initial assessment to discuss career goals and research interests. It is important to take into consideration whether the mentor is a good fit for the mentee and vice versa. This initial assessment utilises the mentor's experience and wider field of view to guide the junior faculty in terms of feasibility and in the creation of realistic goals and bite-size objectives to reach those goals. At the same time, the mentee and mentor should discuss measurable outcomes to the goals proposed by the mentee and the appropriate timeframe within which these goals should be achieved.

A healthy mentorship requires the mentee to adhere to responsibilities; for example, a mentee should not expect authorship of a project if they have not performed their agreed upon duties. Expectations, timeframes, and how one is evaluated should be openly discussed and received in a non-judgmental manner as trust and confidentiality is the foundation of a mentor-mentee relationship.

### Facilitation of Resources

Institutional resources are instrumental to the success of junior faculty. Resources are not always monetary and can be divided into four categories: general, research, teaching and services, which apply to both personnel and items. The availability of resources should be concordant with the institutional expectations of the junior faculty. For example, if junior faculty is expected to publish

heavily on scientific research, besides funding support, they should be allocated the appropriate academic time, facilities and setup where the expected research is performed (research), ability to attend additional courses in terms of utilisation of equipment or extension of knowledge into the subject matter (teaching) and access to research assistants and statisticians (services). As one can see, if any of the resources are deficient, projects fail.

In order to increase opportunities and confidence of the junior faculty member, whenever it is deserved, the department should make junior faculty aware and nominate them for awards, positions, talks on a departmental, institutional and professional organisational level. This is the idea behind "sponsorship" which is different from mentorship with the focus on advocating for, and supporting the career advancement of the junior faculty (Perry & Parikh 2019). While some nominations can be appropriately spontaneous, nominations that require additional time, such as lecture preparation or meeting attendance, should be given with ample notice.

### Mentors-of-the-Moment

This concept incorporates mentoring, workplace culture and engagement of junior staff (Johnson & Smith 2019). It addresses the problems of a formal mentoring programme where it can be hierarchical, and this may not suit all employees and acknowledges the best mentoring programme can falter under a toxic work culture. Formal mentoring programmes also fall prey to seniors only partaking in the programme in name only, as they have been told to "volunteer" by management. When mentoring is not a part of the daily work culture, formal mentoring programmes will not engage or develop junior talent.

Mentor-of-the-moment embeds mentorship in the work culture and all members of the organisation can be active participants with small daily interactions to help juniors grow. These



interactions are informal and short exchanges with the aim to enhance the self-confidence, self-esteem and sense of inclusiveness in the junior faculty. These frequent micro exchanges provide a solid foundation on which trust, collegiality, sponsorship and mentorship can be built on. Examples of mentors-of-the-moment include acknowledging juniors on their achievements in front of others, asking for their perspective, deliberate check-ins to see how they are doing and offer support or resources when appropriate, give and take feedforward, ensure transparency, clarity and accountability.

This particular mentoring style can overcome potential roadblocks in mentorship when the mentor and mentee are of different genders or races. This is especially true in the setting of men being reluctant to initiate formal mentorship with women, as they do not want to be seen as someone who spends a lot of time with the opposite sex or people who avoid cross-race mentorship relationships as they worry whether they would have the culture competence to facilitate a successful mentorship.

**Feedforward**

We need to move away from “feedback” to “feedforward.” The concept of

“feedforward” is rooted in a mentor’s understanding of the mentee’s goals and focuses on the goals and expectations personalised to the junior faculty member rather than following what may merely be arbitrary standards (Kruse 2012)

The theory of feedforward encourages 360 degrees perception of the mentee via informal surveys from those who work with and around the mentee. The use of these surveys has the potential to decrease bias and discrimination, and the transparency of their use can help decrease any potential negative emotions by the mentee, allowing for a more open dialogue and experience. To-and-fro evaluations may also be useful between mentors and mentees, whereby there is an open means of mentee evaluation that can occur without a particular timetable. This allows the junior faculty to take the opportunity to correct any issues as they arise which differs from traditional feedback methods.

**Reduce Impediments**

It is vital to avoid the “catch-22” situation where the junior faculty may find it difficult to say “no” to a senior faculty. There should be an honest and upfront conversation between the mentor and mentee when volunteering

them for committees and projects with regards to how this can contribute to their goals and road to promotion, and to ensure that there is no exploitation (Baerlocher et al. 2011).

The other situation which can arise in institutions with a heavy emphasis on seniority, is that of potential negative consequences which leads the mentee to lose time, energy and even money, or the mentee does not receive credit for their work (Baerlocher et al. 2011).

Lastly, all good work achieved by the junior faculty should be acknowledged and rewarded in proportion of their achievements. Junior faculty should also acknowledge and show appreciation to their mentor.

Engaging junior faculty members early on is essential to ensuring their retention and institutional longevity, thereby allowing them to continue to elevate an institution through scholarship and teaching. However, junior faculty still needs to take ownership and be accountable for their own career pathway and of the opportunities which they have been given.

**Conflict of Interest**

The authors declare no conflict of interest. None of the authors have or had manuscripts published on this subject. ■

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# MRI Portfolio Optimisation

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# Magnet Nursing

## Employee motivation, medical quality and patient satisfaction in unison

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The continuing shortage of qualified care personnel and doctors is forcing hospitals to develop innovative concepts of personnel management in order to attract personnel and bind them over the long term. The concept of ‘Magnet Nursing,’ or the ‘Magnet Hospital,’ which has been practiced successfully in the U.S., provides some insights into a promising new orientation for organising and managing European hospitals as well.

### Key Points

- Staffing and working conditions are the driving factors for achieving a high-quality level of care.
- Economic success directly correlates with a corporate culture that entrenches customer orientation, uncompromising quality and purpose for the employees in the corporate value system.
- Magnet Nursing managers lead through listening, questioning and feedback.
- Quality in medicine and patient experience result from employee satisfaction, which is a consequence of working conditions.
- Actions and behaviours shape attitudes and beliefs rather than vice versa.

The care staff constitutes the largest occupational personnel group at hospitals and care institutions. This group has the most time-intensive and closest contact with patients. Nonetheless, as a result of cost pressure, many hospital managers tend to conduct short-term cost savings through work intensification (the combining of jobs) or even reduction of the care personnel number, instead of using care standards as a basis for problem-solving.

### Context

Hospitals are service enterprises, in which medical services for people (patients) are provided, who generally find themselves in a borderline situation, both physically and psychologically (fear, pain, loss of autonomy). Professionalism, knowledge and empathy on the part of the care personnel largely determine the quality of patient care.

Given the complexity of medical care services (disease-specific, individual

patient provision with diagnostic, therapeutic, care and other services), quality requirements in terms of the ‘confidence good of medical service’ can only be ensured through outstanding communication and cooperation, which is interdisciplinary and intergroup (in the sense of different professional groups).

There is a direct interrelationship between the organisation of work processes, the motivation and professionalism of employees, medical quality

### Magnet Nursing: Input-Output Model

The Magnet Nursing Model implies a cause-and-effect correlation between working conditions and nurse staffing on the one hand, and defined outcome indicators on the other hand

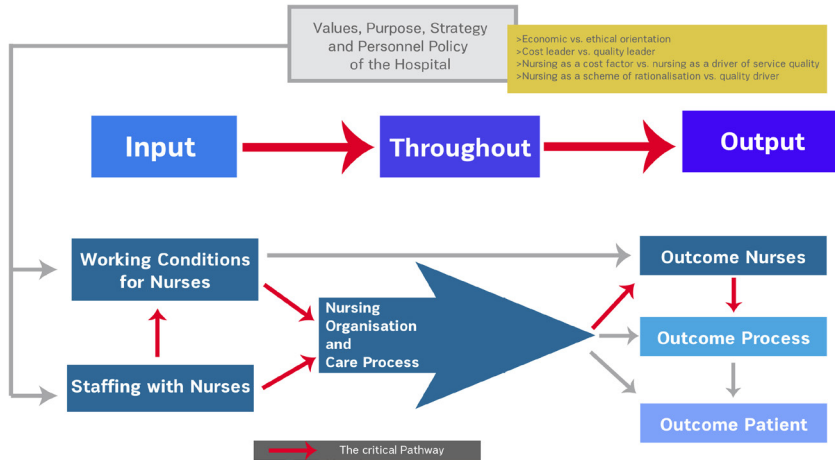


Figure 1. Staffing and Working Conditions are the Driving Factors for Achieving Better Outcome Results in the Long Run.

### 5 Magnet Forces

The most important success factor: the balance between all 5 Magnet Forces

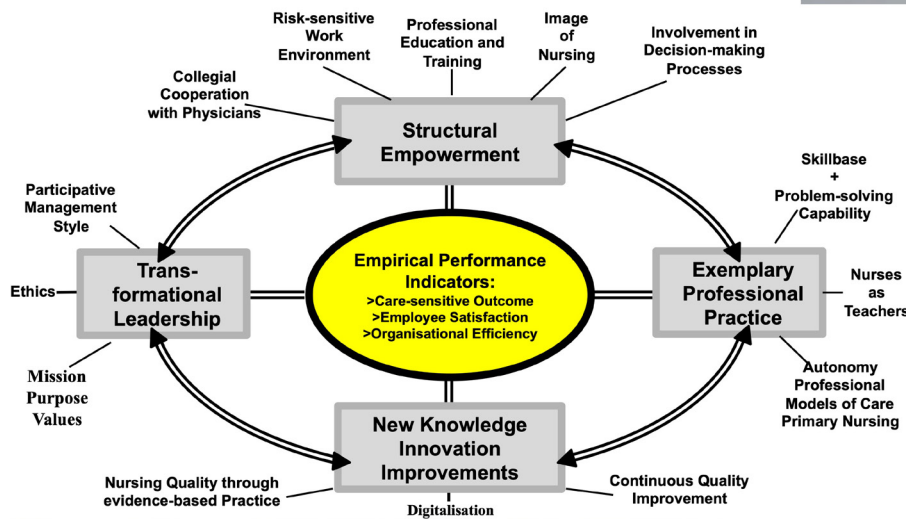


Figure 2. The Model of the 5 Magnet Forces is Only Effective When There is Consistent Implementation.

as well as patient satisfaction (Figure 1). The daily reality in hospitals, by contrast, is all too often characterised by work intensification, time pressure, error-prone work processes,

employee demotivation and patient dissatisfaction. In addition to organisational deficiencies, deficits through work-reducing equipment and insufficiently effective

professional and interdisciplinary cooperation, there are also communication deficits and gradual rationalisation, which lead to burnout syndrome and declining willingness to perform.

Against the background of imminent deficit of qualified care personnel and doctors, and in parallel to the increased demand for medical care performances, the question arises as to the extent can the Magnet Nursing Concept contribute to overcome this dilemma.

### Criteria of Magnet-Hospital: 'Magnet Forces'

The American approach to magnet hospitals is originally based on medical institutions, in which care personnel with excellent subject-related competence contribute to providing outstanding medical services (ANCC 2020; Summers 2020). As such, the patient care process proceeds smoothly and with low risk, innovations are implemented in a timely and effective manner, and patient satisfaction is high (McHugh 2013). Magnet Hospitals direct the care activities in an evidence-based manner, that is subject to an orientation towards care-sensitive performance indicators.

In addition, work satisfaction is high and the fluctuation rate is low. The employer attractiveness of a Magnet Hospital results from the orchestrated implementation of the '14 forces of magnetism' and the '8 principles of action,' which serve as an organisational culture guideline (Peters and Waterman 1982). These criteria are summarised as the model of the '5 Magnet Forces' (Figure 2).

### 'Forces of Magnetism'

The '14 Forces of Magnetism' are the foundation of excellent care services. They aim at establishing participative management, an organisational structure oriented towards delegation and characterised by constructive interaction and transparency, as well as an environment that is safe and promotes healing.

Individual goals and personal interests of the employees are harmonised

with the medical requirements, as well as the business-related imperatives of the hospital business (Figure 3).

### Leadership quality of nursing managers

A nursing manager (NM) is competent in terms of skills, professional experience, effective implementation, and is extremely risk-aware with regard to the patients. Through actively setting an example, providing the necessary resources and practicing a participative leadership style, the process ensures that the daily guiding principles of care are used to the full benefit of the patients. An NM initiates programmes for improving patient safety, optimising work processes and organisational structures as well as ensuring infection prophylaxis. An NM leads by listening, questioning and giving feedback.

### Organisational structure

Flat hierarchies at the ward level and systematic involvement of care personnel in decision-making processes and project groups ensures sound

decision-making, which can be implemented rapidly. An NM is a member of the hospital management and reports to the CEO on a regular basis, as well as to the supervisory board. For medical departments, care area leaders are established, who work together with the department head doctors organising patient care.

### Leadership style

The leaders practice an employee-oriented management style. Reciprocal, inter-hierarchy feedback, agreement on quality objectives, open error management, and suggested improvements are welcome, and participation in decision-making committees is expected. Leaders are accessible to employees ('Open Door Leadership Policy'). The communication culture is open and results-oriented. Decisions are made in interdisciplinary teams, also involving patients and their relatives (informed consent).

### Personnel policy and programmes

Employees receive competitive

salaries that are appropriate in terms of the particular responsibility that they carry. There are also individual performance and success-oriented additional payments based on commitment, collegiality and undertaking project activities for quality improvement – but there is no orientation towards economic goals. Employees have a right to participate in making decisions on work processes, working hours and career perspectives. Shift rotations are regulated in a health-promoting and family-friendly manner. The integration of family and work is an important objective of work formulation. There are transparent possibilities for development in both specialist and management careers. Rotations in new subject areas (e.g. purchasing or medical controlling) enhance the learning potential and knowledge of the entire organisation.

### Professional care models

Care models provide care personnel with a consistent overall responsibility for individual patient care, assign them with clear task areas, and equip them with necessary authority (decision-making, resources). For coordination and implementation of all care measures, there is also organisation-wide, entrepreneurial handling of resources (i.e. willingness to innovate and cost awareness). The care model of choice is that of 'Primary Nursing.'

### Care quality

Care quality is oriented towards the 'Patient first' principle. Accordingly, the leading care personnel are responsible for creating structural conditions, which promote high quality. This applies to the provision of equipment for work simplification (patient lifts, electric beds, mechanical aids for standing up), patient risk reduction (e.g. electronic provision cabinets for avoiding medication errors), and hygiene maintenance (self-cleaning toilet facilities). Care quality is provided on the basis of measurable care-sensitive indicators and the consistent application of Lean Management instruments (e.g.

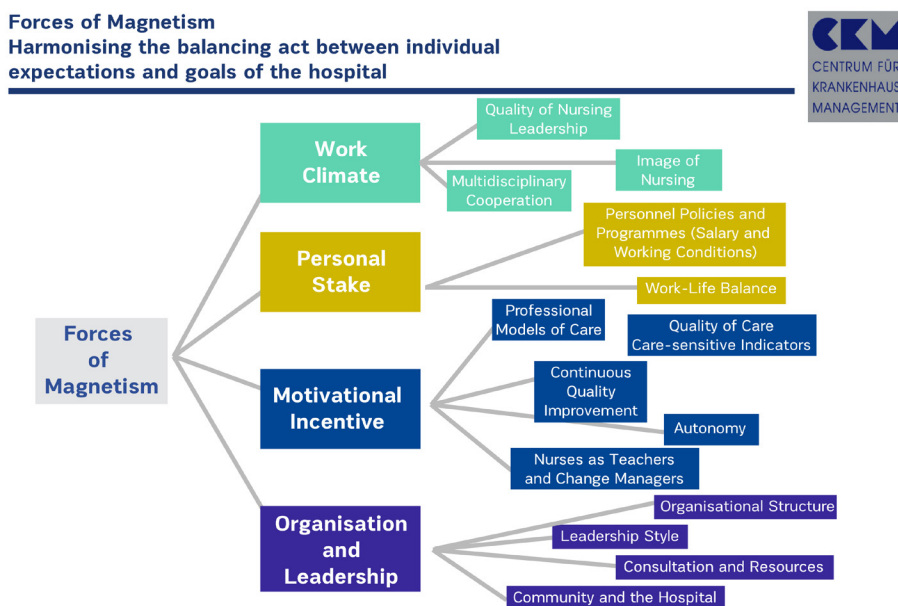


Figure 3. The Construct 'Forces of Magnetism': They Provide Attractive Workplaces, Which Ensure High Quality and Safe Clinical Processes for Patients. Outcome Results in the Long Run.

Liker 2004) with the aim of continuous improvement. These care-sensitive ratios are a precondition for autonomous planning and delivering of care (Figure 4).

### Continuous quality improvement

Care personnel are familiar with the modes of thinking (Kaizen), the methods (PDCA-cycle) and techniques (e.g. Ishikawa-Diagram) of Lean Management, and each employee is expected to apply this knowledge with initiative and continuously, to ensure that process improvements not only benefit patients but also lead to more effective work design.

### Autonomy

Care personnel work independently

improvement and are responsible for the implementation of innovations within the ward processes and procedures.

### Image of care personnel

The work of care personnel is regarded as a substantial success factor within the context of work groups in hospitals, and is associated with a high level of recognition and communication in personal interactions. The hospital management ensures that the care profession is also regarded by the public as valuable, demanding and challenging.

### Interdisciplinary cooperation

Goal-oriented, smoothly functioning interdisciplinary cooperation and intergroup work is the basic condition for the complex medical care of a patient in a

work, to achieve the best possible value and benefit for patients, while at the same time, keeping costs under control. In this manner, specialised functions (e.g. wound management, pain management, triage nursing) and new occupational profiles (e.g. Physician Assistant) contribute to and justify the demands on carers for ongoing qualification and reduce the burden on doctors (e.g. Endo Nurse, Stroke Nurse), also through the increasing transfer of doctors' activities to specifically trained personnel (e.g. Nurse Physician).

### Anchoring within community/region

Magnet hospitals see themselves as an integral component of the community, and support its infrastructural and

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## The daily reality in hospitals is all too often characterised by work intensification, time pressure, error-prone work processes, employee demotivation and patient dissatisfaction

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on the basis of care standards. They themselves recognise care requirements and can determine which measures should be introduced. Autonomy is also achieved through the delegation of tasks, expertise, or authority and responsibility. The provision of care is constantly evaluated through care-sensitive indicators, and based on this, measures are undertaken for continuous improvement.

### Care personnel in various roles

Care personnel are involved as trainers in various educational programmes, both internal and external to a particular hospital. They also participate in and are responsible for scientific projects for examining clinical evidence, alternative forms of patient care, wound management, and so on. Care personnel independently initiate projects for

hospital. It should be conducted in a medically appropriate, ethically oriented manner, with minimal patient risk and the integration of the best possible expert skills as well as economic viability. Mutual respect of the various professional groups is necessary and promoted through a targeted cooperative work programme. Therapy decisions are made according to the principle of 'Shared Decision-Making.'

### Professional human resources development

The organisation consistently places value on formal qualifications, continuous certified training and career planning, allowing for switches between medical-related and management careers. Professionalisation and specialisation are promoted to foster effective delegation, and through the division of

societal development. There are also programmes to counter youth unemployment, campaigns for safety in one's leisure time, and second opinion procedures for practicing doctors. Furthermore, care personnel assume important coordination activities in the context of discharge management, as well as in the aftercare of special patient groups in need of assistance (ALS, paraplegic, stroke and dementia patients), through networking of various service providers (meals-on-wheels, family doctor/specialist doctor, social services, local support services, health-care supply store, care services) directly after discharge.

### Advice and resources

After their hospital stay, patients are also given specialised subject-related advice and supported organisationally.





# What if we Treated Patients More Like Customers?

Author: [Erin Birch](#) | Healthcare Expert | PA Consulting | UK

COVID-19 has ignited the need for data-driven decision making, personalised health-care and digital delivery. How can the NHS become a customer-focused organisation and reimagine healthcare to meet evolving priorities?

## Key Points

- To deliver world-leading health outcomes, the NHS needs to get comfortable with new concepts of healthcare delivery.
- It is now time to consider the full potential of reshaping the NHS's relationship with patients so they are treated more like customers.
- Moving to a customer model would allow the NHS to realise a patient activation dividend, freeing up capacity to focus on those who need the most support.
- The first step to becoming a customer-focused organisation could be to cultivate a vibrant market that encourages new players who bring disruption, technological innovation and ingenuity.

People spend a large proportion of their day interacting with big multinational corporations that are ultra-responsive and hyper-personalised. With so many of our interactions with organisations being virtual, intuitive and personalised, patients' expectations for how they interact with the NHS are changing. This was the case before COVID-19, and these expectations have only increased as a result of the rapid uptake of new technology-enabled service delivery in recent months.

These organisations (Netflix, Amazon, Apple etc.) have two essential characteristics. Firstly, they constantly seek new ways to deploy emerging technology to deliver services. Secondly, they treat people like customers.

To deliver world-leading health outcomes, the NHS needs to get comfortable with both concepts. Signs are very good on the technology front. The speed at which the NHS has been able to move to new digital models of delivery has been incredible. For example, at PA Consulting, our experts supported the

rapid deployment of new technology to deliver virtual consultations. With respect to a particular new platform, this has contributed to the growth of virtual consultations at a rate of around 200 appointments a day.

We have also helped roll out new technologies to the homes of vulnerable and elderly people to enhance their ability to live in their own home and easily connect to support services - 94% of service users feel that the care technology deployed has increased their feeling of safety and security. We have worked with over 20 local health and care economies to harness data in their response efforts. These analytical tools are helping the NHS develop mitigations to the impact of COVID-19 this winter and guide the recovery of elective services, ensuring as much activity is serviced as possible before winter.

As for introducing customer capabilities and culture, there's still a lot to do. And the effects of the lack of customer centricity are clear.

The NHS is a highly efficient system by

global standards, but increasingly standardised pathways of care have unintended consequences. Through our work, we see the NHS over-servicing some patients and under-servicing others, in some cases, spending more money than necessary and still struggling to improve health inequalities. For example, we are working with a health and care economy which has received funding increases year on year and yet sadly has worsening levels of diabetes, late diagnosis of diseases and an increasing gap in life expectancy based on deprivation. A simple measure that could make a difference is capturing the time spent on face to face interactions with people who could safely be serviced virtually and redirecting that resource to tackling areas of greater need.

This experience has led us to consider the full potential of reshaping the NHS's relationship with patients so they are treated more like customers. How might this save money, improve outcomes and capitalise on the digital advancements that have been achieved through the COVID-19 crisis?



### What do Customer Focused Organisations do Differently?

Let's start by thinking through what customer-focused organisations do:

- Customer segmentation.
- Differentiated offers for different customer segments.
- Different allocation of resources for different customer segments.
- Influence customer behaviour, such as through reward schemes.
- AI-enabled marketing.
- Unrelenting focus on customer satisfaction.

this anxiety is understandable, we think it is misplaced. In fact, treating patients like customers could be transformational in helping unlock efficiencies and making sure taxpayers' money is optimised. For example, adults forty-five years or older who sleep fewer than six hours a night are 200 percent more likely to have a heart attack or stroke during their lifetime, as compared with those sleeping seven to eight hours a night. How many people know that and are therefore empowered to make a change to their sleep patterns? Perhaps not many, as two-thirds of adults throughout developed nations

locally through commissioning strategies, incentivising collaboration between local organisations, and designing new outcomes-focused contracts. These are practical ways for the Government to act with greater collective impact.

#### “It's hard to change an organisation as big as the NHS”

Yes, it's hard to change the culture of an organisation as huge as the NHS. But isn't this the perfect time to radically reimagine health and care economies and their potential to meet evolving priorities? A time where

## The NHS is fatigued by structural reorganisation but a healthcare customer revolution is coming

If patients were treated more like customers, we could begin to:

- Use data to better understand people and what they need to be well.
- Use personalised medicine and improve health outcomes.
- Have light-touch, or more intensive models of care based on patient activation/ability to self-manage.
- Incentivise people to stay healthy, rather than just treating people when they become sick.
- Proactively push personalised resources to people to support prevention and self-care.
- Have happier, more engaged and more motivated patients and clinicians.

### Why Has This Not Been Done Before?

People have traditionally had major concerns about shifting the NHS in a customer-centric direction. As we emerge from the COVID-19 crisis, it's arguably now clearer to see how each of these objections can be overcome.

#### “It would increase expectations that we can't afford to meet.”

Some NHS managers fear such an approach will raise patients' expectations beyond the service that the NHS can provide. While

fail to obtain eight hours of nightly sleep. Empowering people with insight to make healthy decisions is immensely valuable in terms of health outcomes and economic outcomes. We see this desire for insight in areas such as the growing business to consumer market for wearables, finger-prick blood tests, genetic testing, and microbiome analysis and 'treatments.' Moving to a customer model would allow the NHS to realise a patient activation dividend, freeing up capacity to focus on those who need the most support.

#### “We don't have the capabilities to respond to customer expectations.”

It's true that it would be hard for the NHS to build the capabilities required to make this transition overnight. However, something that NHS and local government commissioners are skilled at is market development. The first step to becoming a customer-focused organisation could be to cultivate a vibrant market that encourages new players who bring disruption, technological innovation and ingenuity. At a national level, this can be achieved through using the levers of Government such as national and local industrial strategies, investing in skills programmes, tax offsets for health technology companies, and funding incubation of innovation. This can be complemented

we could pivot the healthcare system from a sickness model to a purpose-led and adaptive health and wellness model. For example, supporting and coaching people in relation to their sleeping, eating, alcohol consumption, and exercise as well as all aspects of condition management and medication adherence. These sorts of interventions have a high return on investment, and they go the heart of purpose and what motivates clinicians, nurses and carers: helping people. The NHS is fatigued by structural reorganisation, but in our experience, unwavering from their personal motivation to care. Culture eats policy for breakfast; why not approach change by leveraging cultural strengths?

COVID-19 has ignited even greater appetite for data-driven decision making, personalised healthcare and digital delivery; all advancements that can orientate the healthcare system to a customer footing. And, because of the incredible progress that has been made, we have renewed confidence in overcoming perceived barriers to ambition and pace of transformation. The healthcare customer revolution is coming, and personally I'm very much looking forward to it.

#### Conflict of Interest

None. ■

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COMING SOON...

# Improved Patient Assessment with MR-proADM

Interviewee: [Professor Carlo Tascini](#) | Head of Infectious Diseases Clinic | Udine University Hospital | Italy

Prof. Carlo Tascini is Head of Infectious Diseases Clinic at Udine University Hospital. Prior to that, he was the Head of First Division of Infectious Diseases Unit at Cotugno Hospital. His field of interests include endocarditis, meningitis, sepsis, MDR bacterial infection and fungal infections. HealthManagement.org spoke to Prof. Tascini about the clinical benefits of MR-proADM.



## Key Points

- Biomarkers, as standalone markers, might function as early indicators of microvasculature and endothelial damage.
- MR-proADM may help facilitate safe discharge of patients in the emergency department.
- It can also help in identifying critical patients that require further diagnostic work-up.
- MR-proADM can help guide antibiotic and sepsis-driven adjunctive therapy.
- In COVID-19, it may help identify dysfunction of microvascular and endothelial cells, before the onset of respiratory failure.

## What is mid-regional proadrenomedullin (MR-proADM) and what role does it play in risk assessment in the emergency department and ICU?

Adrenomedullin plays a significant role in vascular permeability, endothelial barrier regulation, and stabilisation of the microcirculation all of which contribute to the development of organ dysfunction and failure in sepsis and septic shock. This biomarker may be induced by bacteria, fungi or viruses. The increase of adrenomedullin is an indicator of organ dysfunction. The incorporation of MR-proADM into an early sepsis management protocol may therefore help guide early diagnostic interventions and facilitate more intensive treatment in these patient groups before development of any further organ dysfunction.

In the ICU, MR-proADM levels can be used to improve risk stratification. Elevated values (>2.5 nmol/L) are indicative of treatment failure & poor outcomes. As such, high MR-proADM values can help guide an escalation in antibiotic and resuscitation therapy in patients at risk of deterioration. Alternatively, low or declining levels of MR-proADM may facilitate early discharge.

## Are there any large scale clinical trials that have demonstrated how MR-proADM can help in safe discharge of low risk patients?

A multinational observational study has demonstrated that MR-proADM can be used to identify patients with low disease severity, who may benefit from early discharge from the ED. Early discharge is essential in maintaining an efficient bed management workflow and may have an overall clinical benefit. Low MR-proADM values can identify patients with low microcirculatory and vascular damage, where additional diagnostic or interventional procedures are not necessary. MR-proADM is able to identify uncomplicated infections with low risk of further progression and therefore might improve in the emergency department (ED) the rate of hospitalisation and out-patient treatment.

A recent multinational observational study by Saeed et al. (2019) indicates that using this biomarker in ED can increase out-patient treatment decisions without increasing subsequent mortality and re-hospitalisation rates. MR-proADM as a standalone marker might be beneficial in high-risk patient settings such as ED, to improve the use of the scarce resources and save costs by increasing outpatient treatment. This needs to be validated in further large studies.

### Can MR-proADM be used in COVID-19 patients to assess the risk of disease progression?

The pathological mechanisms of organ damage in COVID-19 patients remain poorly understood. The multiple organ failure described in COVID-19 suggests involvement of multiple pathway. Endothelial cells (EC) dysfunction could be one of the explanations for organ failures and edema as endotheliitis might be an important, although still underrecognised characteristic of COVID-19 severe disease. SARS-CoV-2 causes vascular barrier breach in the lungs, leading to increased content of fluids and edema, endotheliitis, activation of coagulation, further leading to disseminated intravascular coagulation (DIC) and dysregulation of inflammatory cells. ECs in the lungs have a role in Acute Respiratory Distress Syndrome (ARDS), a major complication in COVID-19. Adrenomedullin (ADM), is essential in maintaining endothelial stability, therefore it is a good biomarker to understand the EC damage.

Montrucchio et al. (2020) demonstrated in a small cohort of COVID-19 patients admitted to ICU, that a higher mortality was found in patients with MR-proADM values higher than 1.8 nmol/L. The logistic regression model revealed that, with an odds ratio equal to 10.2 this biomarker had the best predictive ability for mortality compared to age, gender, procalcitonin (PCT), pC-reactive protein (CRP), presence of diabetes or cardiovascular diseases.

At Udine hospital, analysis of 112 COVID-19 patients admitted to ICU and ID department, an initial value of MR-proADM > 1 nmol/L was associated with reduced PaO<sub>2</sub>/FiO<sub>2</sub> ratio values, less than 250 and increased mortality (*C. Tascini personal experience*).

### What are the cut-off points and conclusions that can be drawn from the results?

Saeed et al. (2019) have studied MR-proADM in the ED. This study found two uses for this biomarker: 1) identify patients with values >1.5 nmol/L that have the potential for further progression of the disease and would benefit from an early escalation of antibiotic and resuscitation treatment and these patients should therefore be treated in the hospital. 2) a reduction of hospitalisation for ED patients without endothelial damage reflected by values < 0.87 nmol/L.

In the first case, the authors were able to identify a subset of patients with increased length of stay, ICU admission and mortality, thus these findings facilitated rapid intervention such as escalation of antibiotics, infusion of fluids, the use of other sepsis therapies and additional diagnostic tests. Particularly high mortality risk was seen for patients with MR-proADM > than 2.5 nmol/L therefore these patients may benefit from immediate admission to a high dependent unit or to the intensive care unit to initiate a more aggressive diagnostic

and therapeutical approach. Several studies have demonstrated that in patients with high MR-proADM, mortality is around 30%.

### What benefit can MR-proADM provide in terms of allocation of scarce resources?

Biomarkers can indicate the onset of microvascular and endothelial damage earlier than the appearance of clear clinical symptoms. As such, they can be used to help rapidly guide the most appropriate diagnostic and therapeutic approach, leading to a better allocation of resources.

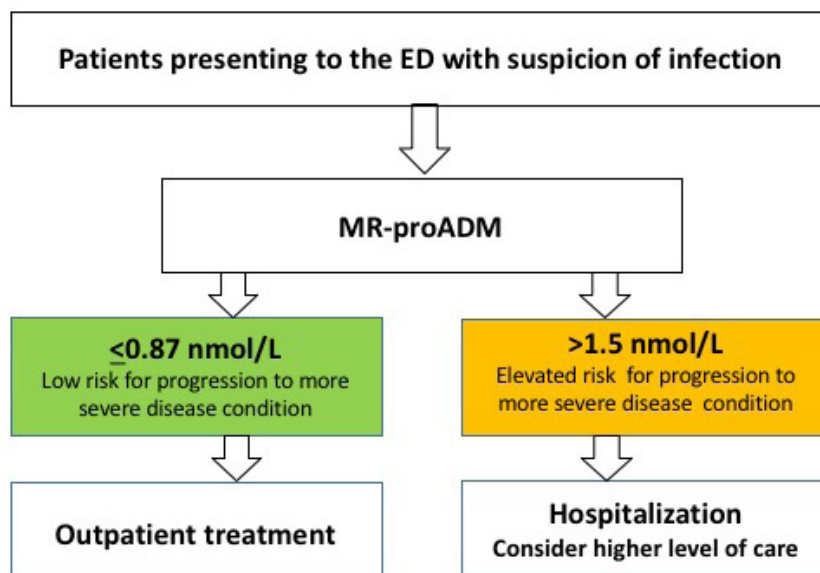
### How does MR-proADM compare to other clinical scores such as SOFA, APACHE, etc.?

Clinical scores such as the Sequential Organ Failure Assessment (SOFA) score and Acute Physiological and Chronic Health Evaluation (APACHE) II score have been developed to assess severity of critical patients. These scores are not able to capture individual organ system dysfunction and they might be too complex to be used in daily routine. A biomarker, if effective, might be more useful than scores, in predicting severity of patients.

MR-proADM was studied by Elke et al. (2018) in a secondary analysis of a large randomised controlled trial on sepsis. The ROC curve and multivariate cox regression identified MR-proADM as the strongest factor, with respect to SOFA and APACHE II, associated with 28-day mortality in total population. They found that initial use of MR-proADM within the first 24 h after sepsis diagnosis resulted in the strongest association with short-term, mid-term and long-term mortality compared to all other biomarkers or clinical scores (including SOFA and APACHE). The addition of MR-proADM increased the accuracy of all other biomarkers and scores. Viaggi et al. (2018) demonstrated that MR-proADM, at least in a single neurointensive ICU, might predict the deterioration of organ dysfunction in infected patients, 24 hours before the SOFA score.

### How is MR-proADM performed?

Mid-regional proadrenomedullin (MR-proADM) is a reliable and stable surrogate biomarker directly reflecting blood concentrations of highly unstable adrenomedullin. ADM is a peptide produced under stress conditions by a variety of tissues and especially by ECs. ADM may have multiple biological functions included diuretic, vasodilatory activities and more important immunomodulatory and microbicidal activities. An automated fluoroimmunoassay is commercially available (B·R·A·H·M·S MR-proADM KRYPTOR, Thermo Fisher Scientific, Hennigsdorf, Germany). EDTA plasma MR-proADM concentrations were measured using the fully automated fluoroimmunoassay on the KRYPTOR platform, with an assay range of 0.05–100 nmol/L.



### Can it facilitate and/or improve clinical decision making?

MR-proADM is a standalone biomarker that may help in facilitating early discharge of patients from ED and ICU and it might be used to escalate antibiotic and fluidic therapies, to make a decision in performing surgery and source control and to apply other therapies used in organ dysfunction such as continuous filtration and other therapies used in organ dysfunction including continuous filtration.

### Can MR-proADM also help guide antibiotic treatment?

As yet, no data is available that directly demonstrates using MR-proADM for antibiotic stewardship. However, it can be used to assess the overall risk for therapeutic failure and poor outcome. Thus, Elke et al. (2018) have demonstrated in their randomised trial about sepsis, that an increasing value of MR-proADM or a continuous elevated value, despite decreasing PCT concentration is associated with subsequent failure of therapy and a poor outcome. In cancer patients with fever, MR-proADM concentration was increased in patients who did not respond to antibiotic

therapy. In these cases antibiotic escalation might be useful. On the other hand, in the case of bacterial meningitis, the use of non bacteriolytic antibiotic, might be associated with better outcome, due to the fact that these antibiotics (e.g. rifampicin) are able to kill bacteria without releasing inflammation mediators. In this subset of patients with high MR-proADM concentration and bacterial meningitis, the early use of non bacteriolytic agents might be associated with increased survival.

### Overall, what would you say are the key clinical benefits offered by MR-proADM?

MR-proADM may help in early discharge of patients from ED with values lower than 0.87 nmol/L and, on the other hand, hospitalisation of patients with values higher than 1.5 nmol/L. Furthermore, it may help to identify critical patients with values > 2.5 nmol/L that deserve further diagnostic work-up and intensify antibiotic and sepsis-driven adjunctive therapy. In COVID-19 it might help to identify patients with microvasculature and ECs dysfunction before that respiratory failure may happen. ■

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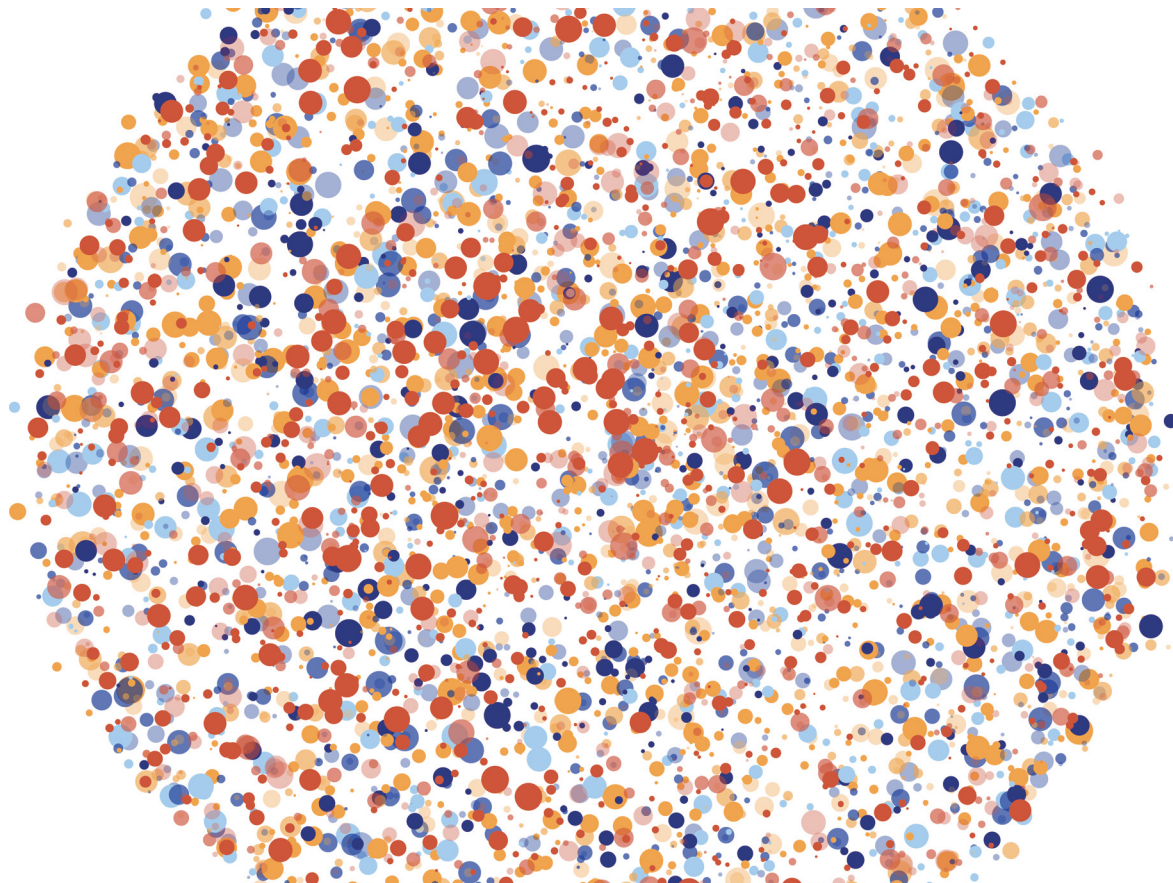
# Deep Mining for Determining Cancer Biomarkers

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Interviewee: [Jonathan Tepper](#) | CEO | Perceptronix Ltd. | UK

Interviewee: [Ahmad Lotfi](#) | Professor of Computational Intelligence | Nottingham Trent University | Nottingham, UK | Visiting Professor | Tokyo Metropolitan University

The use of omics data for knowledge discovery is an approach that can be used for personalised cancer medicine and for a better understanding of cancer genotype and phenotype. Three researchers have developed a deep feature learning model to discover biomarkers that are positively and negatively associated with cancer. HealthManagement.org spoke to Abeer Alzubaidi, Jonathan Tepper and Ahmad Lotfi to find out more about this new approach and its potential.



**What do you think are the most significant limitations in harnessing omics data in the biomedical space?**

Extracting knowledge from omics datasets is a serious challenge for the research community interested in understanding the cancer genotype and phenotype. Such datasets are characterised by high dimensionality and relatively small sample sizes with small signal-to-noise ratios. This significantly challenges existing machine learning-based solutions due to the so-called 'curse of dimensionality' where the addition of new input features typically requires an exponential number of input observations (which are commonly unavailable) to discover the underlying structure of the data that allows these models to generalise well to unseen cases. This also puts great pressure on data mining models that attempt to separate the signal from the noise in a bid to discover robust determinants.

**Describe how the non-linear sparse auto-encoders in your deep learning model work?**

The Sparse Compressed Auto-Encoder (SCAE) is simply a feedforward neural network trained with a variant of back-propagation to reproduce its input signal on its output layer, resulting in a hidden or latent feature layer of neurons representing the underlying transformation performed. The principle idea behind our SCAE model is to transform the original high dimensional omics data into a reduced feature space so that enough of the interesting complexity can be retained whilst not requiring additional observations to further constrain the model. This reduced description of the omics data is further realised through a regularisation technique within SCAE that maximises the likelihood of retaining important input signals describing much of the variance within the data, whilst filtering out the less important and noisy signals.

The Stacked Sparse Compressed Auto-Encoder (SSCAE) is composed of a sequence of SCAE trained in a dependent and co-operative manner, where the hidden feature layer of one model feeds as input to another. The underlying complexity of omics data is compactly represented with multiple levels of abstraction, therefore, we apply a greedy recursive approach to transforming the input signals containing tens of thousands of genes into a hidden representation of a lower dimension and higher abstraction, which is then provided as input to another SCAE, which encodes this further at a higher abstract level and so on. The resulting abstract hidden layer is then provided as input to the final layer of SSCAE (i.e. the output layer), which is a softmax classification layer trained to classify the input as belonging to either a patient with or without cancer.

In addition, we augmented a novel weight interpretation feature into SSCAE such that we were able to determine which original features on the input layer were most highly predictive, positively and negatively associated with the positive patient groups e.g. cancer, ER+/PR+. This method is simply based on computing the integrated weight score for each gene within the original input data that indicates its contribution to the latent representations formed within SSCAE during

learning. This expands our deep learning model to include a feature selection method in addition to the feature extraction capacity already inherent within this paradigm. As a result, two smaller subsets of robust molecular markers are produced, one corresponding to those genes that are highly expressed for most of the patients from the positive group compared to the negatives; and the other subset refers to those genes that are highly expressed for most of the samples in the negative group compared to the positives. These subsets of robust biomarkers are then validated by training an independent classifier, such as a Support Vector Machine (SVM), to construct highly accurate classifier systems.

**In what genotype and phenotype scenarios have you implemented your model and what outcomes have you detected?**

It is well-known that much more accurate machine-learning methods are required to specify and measure phenotypes of complex diseases such as cancer. In particular, our focus has specifically been to reduce the amount of spurious or false positive associations within sophisticated classifier-based systems by intelligent feature selection and extraction. Moreover, if it is possible to identify robust biomarkers for cancer this will help standardise the definition of the disease to facilitate the interpretation and reproducibility of methods and results. However, we recognise this is against the challenging backdrop of data samples that are of very high dimensionality and relatively low sample sizes.

We utilised proteomic and genomic data sets to discover the phenotypes that underlie the variations apparent between the cancer and control patient groups. Fundamentally, two types of outcomes were revealed by our deep mining model, both indicating strong likelihoods of a patient having cancer. The first outcome indicated a subset of highly positively-weighted genes whereby the amplifications and gains in the gene expression levels were associated with the likelihood of a patient having cancer. Conversely, the second outcome revealed another subset of genes that were highly negatively-weighted and coincided with significant downregulation in the gene expression levels, and again indicated the strong likelihood of a patient having cancer.

**How has your model ameliorated existing models of cancer biomarker identification?**

As mentioned earlier, extracting knowledge from omics datasets is a serious challenge for machine learning-based solutions due to the 'curse of dimensionality.' Whilst some existing deep learning (neural network models with many hidden layers) approaches appear able to handle 'curse of dimensionality' issues and improve generalisability, this is typically at the expense of long training times, a need for substantial data to train the models, and lack of transparency in that it is not able to unambiguously state which input features are responsible for its behaviour.



To alleviate the limitations of existing approaches, we introduced SSCAE, a deep feature mining model with an explanatory technique that can be used for discovering robust high-level abstract representations from high dimensional small sample size omics datasets and reveal key determinants underlying these latent representations. Unlike other systems, SSCAE can perform deep classification whilst simultaneously revealing the key input features underlying its hidden representations. SSCAE's output decisions were further validated using appropriate evaluation metrics and independent model

biomedical community should explore further. Also, with the rise of high quality integrated and multi-modal omics data, such as the TCGA database which contains a combination of genomic, epigenomic, proteomic, imaging and clinical data for matched patient groups, will enable us to develop sophisticated 'integrative models' that may reveal even more valuable indicators of disease. We feel this will provide a sound basis for the development of more effective diagnostic and prognostic systems in the future.

## Extracting knowledge from omics datasets is a serious challenge for machine learning-based solutions due to the curse of dimensionality

validations, thus providing significant confidence as to the relevance, robustness, and reproducibility of the discovered biomarkers.

### How do you think medicine and research could collaborate more efficiently and effectively for better diagnosis of cancer?

A significant obstacle for biomarker discovery research remains the need for more effective interdisciplinary research environments, involving academics, clinicians and government working in a co-ordinated and prioritised manner. There are relatively few examples of situations where novel omics biomarkers originating from the cancer research community has found its way into routine clinical practice. Effective interdisciplinary research is therefore paramount if findings from state-of-the-art machine learning research is to be truly exploited and brought into the service of precision medicine e.g. data scientists should have clear routes of access to clinicians when evaluating genes identified by their machine learning methods. Similarly, clinicians must have fluid access to data scientists and bioinformaticians when requiring solutions to real-world problems, such as understanding the genetic make-up of new and emerging diseases or pandemics e.g., viruses such as COVID-19 and Ebola.

### Based on the outcomes of your research, what do you think is the next stage? Is there scope to take your research further?

Moving forward, we will investigate the capacity of SSCAE to detect generic biomarkers for selected cancers across a range of independent high-quality genomic samples collected from different studies. This will further add confidence to the significance of the generic biomarkers already discovered by SSCAE and indicate which of these the academic and wider

### How do you see your model being used in a real-world setting?

SSCAE could be realised as an essential software tool for bioinformaticians and clinicians. Bioinformaticians would use SSCAE for research and development purposes, evaluating various panels of genetic biomarkers for an array of different diseases with our deep mining model providing state-of-the-art analytics to further their research. Clinicians would use SSCAE optimised for specific diseases so that they can interrogate the software tool for biomarkers relating to specific cancers to establish whether or not patients have cancer and if so, to inform specific treatment patterns and protocols (subject to individual patient biomarkers being available to SSCAE).

### Are there any particular cancers that your approach is most suitable for?

Our research provided much support for the strong association between gene expression and oestrogen and progesterone receptors and the development and treatment of breast cancer. However, our deep mining approach to feature extraction and selection is generic, and can therefore be applied to most, if not all cancers, where an underlying cause is believed to have a strong genetic component.

In our next paper, we will be presenting the outcomes of our experiments with our deep mining model for exploring the association between mRNA expression data and the positivity of both ER and PR receptors in breast cancer.

### Conflict of Interest

None. ■

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# How AI Orchestration Will be Music to the Ears of Weary Radiologists

Author: [André da Silveira](#) | Senior Product Marketing Manager | GE Healthcare

How can health organisations speed up AI adoption to gain efficiency, quality and resourcing advantages, without a slow and complex set-up process that could add to the cognitive overload already being experienced by radiologists?



## Key Points

- Coronavirus has generated greater empathy for the radiology profession and has highlighted the need for a more agile approach to tackling clinical overload in hospitals.
- The COVID-19 pandemic has forced nations to delay routine imaging procedures resulting in a new imaging backlog to address.
- Health data and Artificial Intelligence could be potential solutions to deal with these new challenges.
- GE Healthcare has a ready supply of innovative and proven deep-learning and AI technologies plus the know-how to put it all together quickly and easily.

Well before 'Coronavirus' entered our vocabulary, stories about clinician burnout, radiologist retirements and health workforce shortages were hitting the headlines. Now, as the virus pandemic has cascaded across the globe, greater empathy has been generated for a tired health profession, and a more agile approach to tackling clinical overload in hospitals forced upon most of the world. Digital solutions have great influence enabling an environment and a workflow that help to reduce clinician burnout helping to improve efficiencies at the same time, which are so important in a time when healthcare providers are shifting focus and capacity to respond to COVID-19 cases.

In addition to a decade of growing resourcing pressures across Europe, nations have now had to delay routine imaging procedures<sup>1</sup> such as CT scans as we deal with a raging infectious emergency. Meaning that today, it is not just increasing patient numbers and ageing populations putting pressure on our health service, but in some areas, we also now have a new imaging backlog to address.

The advantages of health data and Artificial Intelligence (AI) are being positively lauded as a solution to solve the challenges in our current, new times, aiding clinicians with

quick, confident and accurate decision support plus more efficient workflows, which could help to reduce repetitive tasks and errors. This, in turn, will benefit clinical teams in both steering the diagnostic pathway and the patients they serve.

## Choice of AI is Ready to Transform Imaging Workflows

If we cast our minds back only a year, there was plenty of dialogue in the health imaging space about embracing AI and championing the proliferation of AI solutions coming to market. Indeed, over the last couple of years there has been over four billion dollars of investment in imaging AI start-ups.<sup>2,3</sup> The choice of solutions is now out there and the evidence growing of how deep learning and algorithms built from data can be just as good as a human reader.<sup>4</sup>

But the big question remains: how can health organisations speed up AI adoption to gain the efficiency, quality and resourcing advantages that are promised, without a slow and complex set-up process that could add to the cognitive overload already being experienced by radiologists?

## Empowering Radiologists by Reducing the Complexity of AI Deployment

Recent research<sup>5</sup> has given insights into how health organisations wish to achieve AI integration in imaging departments. 81% stated that they would prefer to get AI from an existing PACS vendor in existing PACS workflow – they don't want a different workflow for AI. Furthermore, the quick experimentation with comparing parametrisation models were high on the AI wish list along with no extra clicks, no separate interfaces and no new user experiences to learn. People want AI, but built seamlessly into the workflow, which, in fact, should be no surprise given that, when done well, AI should be totally invisible.

Therefore, the answer lies in embracing innovative solutions from new to market and cutting-edge players orchestrated by a proven, trusted and long-term healthcare partner.

Seizing the challenge, GE Healthcare's Edison Open AI Orchestrator\* enables the quick deployment of AI and non-AI based clinical applications, easy configuration of workflow and algorithm parameters. This will provide the reality to easily experiment, measure and optimise results with GE and third-party AI applications. In summary, clinical workforce orchestration brings AI applications into the workflow from one or more DICOM devices. This will help clinicians to reduce repetitive workload so that they can have more time to focus on specific patient cases and expand their holistic decision support where patients need it most.

## Simplifying & Automating the Route to Operational AI

This approach overcomes the irony of some technologies being designed to help productivity actually adding work to an already beleaguered workforce. It creates a much smoother and simpler route to arriving at operational AI by automating the process and breaking down cognitive change barriers and fears of extra set-up workload. It can be brought into practice without needing to learn new tools or new interfaces.

Arriving at the desired AI destination utilising a flexible workflow management system revolves around the three Rs:

- What route is the data coming from – a device, PACS, or a vendor neutral archive?\*
- What are the rules for the algorithms – patient age, modality, or body part?



- What role\*\* do we want the algorithm to apply to the rules – for example, count lung nodules?

It is this systematic framework of automation that will help healthcare providers scale with AI and quickly integrate the algorithms they need to experiment and deploy into real clinical conversations.

## Seizing the Moment to Make Positive Change for the Future

Never before have we asked for so much from our healthcare professionals. 2020 will be remembered for the unprecedented levels of pressure imposed on the health industry that pushed institutions, morale and medicine to its limits. But as we reflect on the challenges faced, great opportunities will arise.

It is clear, healthcare needs to change to meet capacity challenges, futureproof against unexpected events and give clinicians an extra helping hand. We have a ready supply of innovative and proven deep learning and AI technologies plus the know-how to put it all together quickly and easily. Now is the time to seize the energy and expertise from AI developments and absorb the strength of an established global healthcare partner like GE Healthcare. Let's orchestrate AI without complexity or extra headaches and improve workflow to lift the spirits of a tired and weary health imaging workforce. ■

\*Edison Open AI Orchestrator is validated with Centricity PACS V7 and Centricity Universal Viewer V7. It is still not open for other solutions.


\*\*The role is based on the approved intended use of the AI algorithm.


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# Smart Diagnostics with Wearable Devices: Principles and Applications

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Life expectancy has increased in the past few decades especially in developing countries, but quality of life of older population can be severely impacted by conditions such as neurodegenerative diseases (dementia, Alzheimer's, Parkinson's, etc.). Early detection and treatment of such conditions is key to increasing quality of life for patients and families. Smart diagnostic methods and tools based on wearable devices and artificial intelligence offer potential for better management and treatment.



## Key Points

- Life expectancy is increasing especially in developing and low-income countries.
- Quality of life does not always increase as rapidly because of different factors, not least neurodegenerative diseases.
- Healthcare and social costs of neurodegenerative diseases are increasing, and new methods to improve treatments and quality of life are necessary.
- Wearable devices and AI can act on large quantities of different types of data and allow early detection, remote diagnostics and personalised treatments
- A case study on automated Parkinson's disease detection and treatment analysis has been highlighted.

## 21st Century Problem

According to the World report on ageing and health (WHO 2015), expectancy of life has dramatically increased in the last decades. As reported, "a child born in Brazil or Myanmar in 2015 can expect to live 20 years longer than one born in those countries just 50 years ago."

However, despite the strong evidence that older people are living longer, particularly in high-income countries, the quality of life during these extra years is quite unclear (Crimmins and Beltrán-Sánchez 2011).

Among the most common consequences of ageing

population, neurodegenerative diseases are rapidly growing and represent one of the major causes of disability and dependency among older people worldwide.

The total number of people with dementia is projected to reach 82 million in 2030 and 152 million in 2050. Dementia is a broad category of neurodegenerative diseases, which impact the ability to perform normal activities, think and remember, with a devastating impact not only on the affected people, but also their family and society at large.

Alzheimer's disease (AD), Parkinson's disease (PD) and



amyotrophic lateral sclerosis (ALS) are among the most common neurodegenerative diseases together affecting over 50 million people worldwide, with almost 10 million new cases every year according to the World Health Organization (2019). Several studies have attempted to estimate the extent of the issue in different parts of the world (Kowal et al. 2013, Mehta et al. 2014, Alzheimer's Association 2013).

### How Can We Address the Problem?

To respond to the continuous population increase and ageing, to the effects and consequences of neurodegenerative diseases, the global healthcare systems must review their care approaches and look at long-term sustainability of the management of cases and the costs sustained by the hospitals and by the charged families.

Several methodologies have been defined over the years to improve care capability and efficiency and demonstrate high potential to improve diseases prevention, remote monitoring and smart diagnosis for dementia. Wearable devices play a major role in such methodologies and have been proven to be effective in different strategies.

#### Disease prevention

Studies show that people can reduce their risk of dementia, depression, obesity, non-communicable diseases and improve their quality of life by getting regular exercise, not smoking, avoiding harmful use of alcohol, controlling their weight, adhering to a healthy diet, and maintaining healthy blood pressure, cholesterol and blood sugar levels. In general, preserving a healthy lifestyle is the basis for preventing ageing-related diseases and ensuring higher life quality among adults as well as elderly (Alwan

2011). Plenty of wearables and smartphone-based applications and studies about food consumption (Fuchs et al. 2019), activity performance (Manea and Wac 2018), sleep quality (Ciman and Wac 2019), and stress monitoring (Can et al. 2019) have been developed over the last few years. The pervasiveness of wearables permits to monitor many of the user's parameters and potentially influence their health. Last, improvements on machine learning algorithms implemented in wearable devices enable to support and suggest how to improve healthy behaviours.

#### Remote monitoring

According to E.J. Topol (2019), wearable sensors have the potential to pre-empt patients being hospitalised in the future reducing the costs of care without sacrificing convenience and comfort for patient and family. Remote monitoring solutions include different applications, such as activity monitoring, falls detection, falls prevention, assisted living, remote hospitalisation and rehabilitation. Activity monitoring and falls detection systems based on machine learning techniques are generally fed by inertial data from wearable devices, such as the accelerometer and the gyroscope. Assistance living and remote rehabilitation use smart technology to share information between wearable devices and home sensors (see Baig et al. 2019 for further details).

#### Smart diagnosis

Wearable devices are valid instruments for dementia's smart diagnosis. As mentioned above, dementia is a progressive degenerative process. All dementia phases require to be continuously monitored to estimate the disease's decline and gravity and promptly intervene with





medical decisions and supports. Wearables can aid and support elderly people without being invasive and, at the same time, are helpful technologies for smart diagnosis. Thus, wearables can monitor changes in behaviour, detect dangerous events, and predict the state of the disease (Mohamedali and Matorian 2016).

### Wearable Technology and Big Data

Over the past decade, considerable progress in hardware and software has modified the habits of individuals, society and business. On one hand, the micro-electro-mechanical systems (MEMS) have reduced sensor size, cost and power needs, while sensor capacity, precision and accuracy have increased. On the other hand, the spread of the Internet of Things (IoT) has enabled and accelerated fast connections between devices, objects and environments.

Modern devices are extremely interconnected, accessible to people and effective in terms of capability to collect, share and analyse large amounts of data. Among them, wearable devices have gained more and more attention in many research fields, not least in healthcare.

Among artificial intelligence (AI) algorithms, machine learning and deep learning methods have seen increasing success for Big Data analysis. Based on data-driven approaches, they are powerful algorithms able to classify and predict clinical outcomes, extract high level information, and identify data patterns.

Nowadays, most wearable devices are equipped with highly performing machine learning algorithms, which allow to monitor our daily lifestyle and healthcare (see Witt et al. 2019 for a comprehensive study).

### Case Study: Parkinson's Disease Classification

An estimated 6.1 million individuals globally had a Parkinson's disease diagnosis in 2016, 2.4 times higher than in 1990. This increasing prevalence was attributed to improved methods used to detect and diagnose Parkinson's disease, greater awareness of the disease, ageing populations, longer life expectancy, and possibly increased environmental exposures (e.g. pesticides, solvents, metals) associated with industrialisation (Feigin et al. 2019).

The quality of life of Parkinson's affected patients may

## The pervasiveness of wearables permits to monitor many of the user's parameters and potentially influence their health

Wearable devices encompass all accessories attached to the person's body or clothing incorporating computer technologies, such as smart clothing and ear-worn devices (Godfrey et al. 2018). They are usually fully equipped with many microsensors, such as accelerometer, gyroscope, or GPS, and can be easily integrated with external sensors. Thus, a simple smartphone can capture attributes, such as motion, location, temperature, ECG, blood insulin level and many other parameters from the user. These parameters are precious information for many healthcare applications.

The main characteristic, which makes wearables so attractive, is their pervasiveness. Indeed, wearables such as smartphones and smartwatches are basically designed to provide online almost all services that a person needs to access during their daily activities. For instance, they allow the user to connect with people, read emails and news, play games and watch videos. At the same time, the user can track many other activities, e.g. sports and nutrition, sleep quality, stress level and even disease symptoms. It follows that a simple smartphone becomes a useful, even critical tool for our working and free time as well as for our healthcare monitoring. All the information recorded by wearables generate a considerable amount of data, often characterised as Big Data.

improve with an early, personalised and accurate diagnosis. In these terms, wearable technologies can drastically help clinicians to perform early and personalised diagnosis over time. Plenty of studies have demonstrated the power of wearable devices and machine learning techniques. According to Rovini and colleagues (2017), five critical fields of application cover the entire pathology progression: (1) early diagnosis, (2) tremor, (3) body motion analysis, (4) motor fluctuations and ON-OFF phases, and (5) home and long-term monitoring.

In the following case study description, we will restrict to (4) as it is the focus of the investigations of the authors at the CERN openlab in Geneva. Parkinson's disease patients exhibit motor symptoms such as bradykinesia, tremor and rigidity. Treatments are based on dopaminergic medicine, which leads the patient into two states: the 'on' state where the effect of the medicine is present and the 'off' state where the effect is absent in the patient. Consequently, motor symptoms fluctuate depending on the effect of the medication. Therefore, most clinical and research studies focus on recognising and stabilising fluctuating motor symptoms (Aich et al. 2020).

Data of 15 individuals have been collected in a real scenario for several months using the accelerometer and

the gyroscope sensors embedded in a smartwatch and a smartphone. Data have been self-annotated in a range from 0 to 4 (0=on, 4=off) and organised in 20-minute segments. Sampling rate and units of measurement have been normalised. A low-pass filter is used to eliminate instrumental data noises and the effects of body-wide motions (such as walking or moving hands and arms during speech). Data was then subdivided into segments (also called windows) of a given length (for example, 20 minutes of accelerometer data can be split into windows of 1 second), and the windows overlapped to decrease the effect of artefacts at the boundaries. Segmentation permits to decrease the computational time during the feature extraction phase, while at the same increasing the size of the algorithm's input samples.

The major difficulty in achieving sufficient performance encountered in the analysis was indeed related to the relatively small size of the dataset. Another challenge was due to the data acquisition scenario itself. Data collected from real activities are usually very noisy because the use of wearables cannot be precisely controlled. Users are free to wear or not wear the device. The activity that the subject is performing can interfere with the measurements and is often interrupted. Furthermore, the data presents intrinsic variabilities, namely the intra-subject and inter-subject variability. The intra-subject variability means that the same severity level presents different signals for the same subject. The inter-subject variability means that same severity levels have different signals for different subjects. Consequently, the algorithm can struggle to generalise the severity level from data, and estimating a one-to-one

signal-severity association becomes rather complex.

In the specific study, machine learning techniques, such as random forest and support vector machines (SVMs), have been preferred over deep learning strategies. It has been shown that ensemble classifier with random forest achieved the best performance. Deep learning algorithms have been also trained, but performance over the limited amount of available data is so far not satisfying.

In the literature, promising results have so far been achieved from SVMs, random forest, k-Nearest Neighbors and Naive Bayesian networks (Aich et al. 2020). Neural networks (MLP) algorithms have been also experimented with (Keijsers et al. 2006) as well as convolutional neural networks (Um et al. 2018).

Although the estimation of 'on' and 'off' state remains challenging due to its strong dependence on the disease stage and on the patient, the current preliminary results show the potential to improve diagnostics and the quality of life of patients by monitoring the effect of treatments and assisting the doctors in defining effective, personalised dosage and intervals.

New technologies have allowed wearable devices to spread in the population. The capability of machine learning algorithms to early detect and monitor neurodegenerative diseases has been drastically improving recently. It is realistic that with the growing use of medical and paramedical devices, increasing amounts of good quality data and improvements in AI algorithms, more flexible, low-cost and high-performing treatments and quality of life conditions will soon become more than a promising idea. ■

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# Improving Diagnosis Through Technology

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As we continue to explore how technology can be used in the diagnostic process, we need to ensure that technology drives diagnostic quality, improving the connection between clinicians and patients in order to provide safe, effective and efficient care.

## Key Points

- With the rapid advances in healthcare technology, careful consideration is needed as to how to integrate it into the clinical diagnostic processes.
- Technology interventions that improve diagnostic quality and safety must consider not only individual cognitive factors but also system factors.
- Five drivers are described, which are key to improving diagnostic quality.
- The COVID-19 pandemic has seen increased adoption of telehealth, but the challenges of this format, including for diagnostics, are yet to be identified.

Evolving technology in healthcare continues to shape the way we provide care to patients. Advances in artificial intelligence, data generated by patients using wearable and smartphone technology, and the involvement of technology companies, such as Google, Apple and Amazon, in healthcare hold great promise in improving clinicians' ability to diagnose and treat patients, as well as improving quality and safety of care. However, safe use of technology and using technology to improve safety requires careful consideration of how it will be integrated into clinical diagnostic processes and how it can enhance communication between patients and clinicians.

Safe, effective and efficient care starts with the diagnosis. Unfortunately, the World Health Organization (2016) reports that diagnostic errors are relatively common and most people will likely experience a diagnostic error in their lifetime, sometimes with devastating consequences. While this finding relies primarily on U.S. data, evidence suggests that same is true in Europe and Asia. Working in partnership with patients, their families, the healthcare community and interested stakeholders, the Society to Improve Diagnosis in Medicine ([SIDM](#)) seeks to catalyse and lead change to improve diagnosis and eliminate harm from diagnostic error. Diagnostic error is defined as "the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient" (National Academies of Sciences, Engineering, and Medicine 2015).

## Five Drivers for Diagnostic Quality

Because the diagnostic process can be complex, technology interventions that improve diagnostic quality and safety must consider not only individual cognitive factors but also system factors. Taking these factors into consideration, SIDM, in collaboration with the Health Research and Educational Trust (HRET) Hospital Improvement Innovation Network (HIIN), developed a [Change Package](#) that identified five drivers that improve diagnostic quality (Health Research & Educational Trust 2018).

• **Effective teamwork** – refers to skills and competencies of an interdependent, multidisciplinary team that includes patients and their families. The teams apply safety culture principles and practices focussed on active engagement of patients, families and caregivers. Making explicit each team member's role and responsibilities in the diagnostic process, then reinforcing these expectations regularly throughout a patient's clinical visit is vital. Organisations must also build in structures (i.e. processes, technology, or tools) to support and ensure effective communication amongst care team members and during handoffs.

• **Reliable diagnostic process** – describes the system of people, processes and environment involved in achieving accurate, timely and communicated diagnosis. Specifically, this refers to organisational structures that optimise diagnostic safety, clinical operations and workflow that supports

accurate and timely clinical information, and processes that ensure accessibility to specialty expertise. This can include forcing functions to help manage alerts and results or mechanisms for patients and families to provide ongoing feedback on the diagnostic process.

- **Engaged patients and family members** – refers to actions taken by the patient and family members working in active partnership with the care team. Engaged patients are empowered to participate in their care and participate in shared decision-making about goals related to diagnosis and care. Patients and families can also engage at an organisational level through participation in advisory councils and quality improvement teams.

- **Optimising cognitive performance** – refers to supporting the process of clinical reasoning including the integration of clinical knowledge and information derived from the patient, family or other members of the care team. This includes effective clinical decision support, education and forums that foster clinical expertise, as well as techniques that encourage reflection on clinical reasoning and decisions.

- **Robust learning systems** – the structures and processes for creating, retaining and transferring knowledge within a team to support organisational learning. This refers to formal integration of diagnostic quality and safety into organisational performance improvement. Activities can include root cause analysis of diagnostic error to methods for providing feedback on diagnostic performance for learning and improvement.

Technology interventions can target a single driver, but typically have greater impact and effectiveness when they address multiple drivers. For example, technology that increases patient, family and caregiver access to the clinical documentation (e.g. [OpenNotes](#)), enhances transparency, promotes ‘effective teamwork’ amongst care team members, and facilitates ‘engaged patients and family members.’ When patients and families review the clinical documentation and provide feedback to the clinician on diagnostic performance, it supports a more ‘robust learning system.’ Data mining approaches have been employed to support ‘reliable diagnostic processes’ by identifying delayed tests and missed follow-up appointments (Evenson and Kerby 2018). Patients and clinicians can then be contacted to reduce preventable delays in diagnosis supporting effective teamwork and robust learning systems. Machine learning and collective intelligence have been used to develop clinical decision support tools to optimise ‘cognitive performance’ and overcome biases (i.e. VisualDx, Isabel, [Dxplain](#), or [Human Dx](#)). These approaches

have also been used to support visual assessments in radiology and pathology supporting reliable diagnostic processes and cognitive performance.

### New Challenges

Because of the rapid spread of COVID-19, in-person visits to hospitals and care centres have been vastly limited, causing the widespread and unprecedented adoption of telemedicine. Telemedicine allows patients, families and their caregivers who are safer at home to access health care and can address all the drivers that improve diagnostic quality. However, little is known at present about the impact this rapid shift will have on diagnostic quality and safety.

To better understand how telemedicine is accommodating diagnosis, SIDM and multiple collaborators have begun work on a Patient-Centered Outcomes Research Institute ([PCORI](#)) funded project to identify issues in most critical need of study and research funding. Issues such as best methods for providing a diagnosis virtually (‘telediagnosis’ or ‘TeleDx’), understanding how to appropriately triage patients with new complaints, and determine when TeleDx is feasible or when an in-person visit is warranted will be explored. Previous research has documented that some uses of telemedicine aid in the diagnostic process and mitigate risk of some errors, but it remains to be seen whether expanded use of TeleDx will lead to new types of diagnostic errors, replicate similar errors to those seen in in-person care settings, or perhaps even improve diagnostic quality. The answer to these questions will require gathering on-the-ground perspectives of patients, clinicians, clinical practices, telemedicine providers, and hospitals and health systems.

The COVID-19 pandemic has taken a devastating toll on human lives and has strained healthcare resources while transforming, in real time, the way we deliver care and use technology without fully understanding the benefits and pitfalls of these changes. Aligning technology interventions with the drivers detailed in the HRET/SIDM Change Package will help to enhance and improve diagnostic quality and safety. When the technology is not in alignment, it can add to clinical, administrative, or cognitive burden, create barriers to communication between patients and clinicians, or at worst cause delays in treatment or incorrect diagnosis, leading to patient harm. As we continue this journey, focus should be maintained on ensuring that technology drives diagnostic quality, improving the connection between clinicians and patients in order to provide safe, effective and efficient care. ■

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# Artificial Intelligence in Breast Imaging Will Shift the Landscape

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The development and refinement of Artificial Intelligence (AI) for use in radiology practice continues. However, this development leads to many questions and concerns. Prof. Baker provides an overview.

The development and refinement of Artificial Intelligence (AI) for use in radiology practice is advancing. Scientific journals continue to publish promising data on AI performance, including a recent report published in *Nature* entitled “International Evaluation of an AI system for Breast Cancer Screening” by McKinney et al. (2020). In this study, two large data sets were evaluated, one from the UK consisting of the records of mammographic evaluations of more than 25000 women at two English screening sites and the other from an American academic medical centre at which, over 17 years, 3097 mammograms were assessed. In both nation’s collections, the initial examinations were supplemented by one or several follow-up studies - at three years in England and every one-to-two years in the US. In both populations, the results revealed a reduction of 5.7% and 1.2% (USA and UK) in false positives and 9.4% and 2.7% (USA and UK) in false negatives.

If further studies confirm the superiority of AI as a means of rendering readings of breast lesions and/or the establishment of mortality reduction, a possible concatenation of disruptive outcomes may be seen. A comparison study may be launched assessing the capability of artificial intelligence in the diagnosis of an abnormality as rendered by MR, with an anticipated confirmation of AI’s superiority in regard to sensitivity and specificity. Hence, if the incorporation of either, or both, mammography and breast MR AI becomes adopted by even a few pioneers, so to speak, then, the setting of breast diagnosis will be called into question.

The issue likely to emerge will be the on-site role of a radiologist. Should one be available for diagnostic purposes, if his or her reading will be shown to be inferior to those realised through AI assessment? No machine or algorithm alone can perform biopsies – although that possibility is not impossible to imagine. Yet does the biopsy operator need to be adjacent to a diagnostic facility?

Remember also that mammography and MR are nearly

always performed on healthy, mobile women, usually in no distress except for anxiety in anticipation of the study. Does she need to come to a hospital to have the examination? Does she need to go to a breast centre separately defined but still staffed with radiologists? Or should breast diagnosis be done not at a physical centre, but at a public health facility, as routine and as private as other routine gynaecologic screening functions, separate from the provocative nature of a clinic that cares for the sick?

AI more fully realised offers the promise of a procedure performed on otherwise well women who need to get it over with, with as little pressure and intimidation as possible. In this scenario, where would the place be for a radiologist if a superior means of diagnosis exceeding his or her capabilities has been established? Would the radiologist be held responsible for determination of the presence or absence of cancer made by an algorithm? And if an aberrant AI diagnosis is involved, where would the responsibility of an error be placed? If it remains with the radiologist, he or she will bear the major risk without a means of defence. If the radiologist is absolved, or now irrelevant, the facility in which the study was performed and the diagnosis rendered could be held culpable.

Questions such as these will continue to be raised as more promising data on AI in radiology emerges. This one study can be considered a landmark article in its outcomes, scope, and publication in a high impact journal. The disruption is yet to come, but whether it is coming is now a settled question.

## Conflict of Interest

None. ■

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# A Snapshot of Imaging Technology

## Exciting Developments and When to Expect Them

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Conversations with thousands of clinicians have given KLAS Research a picture of the current trends in medical imaging technology. Current users' successes and failures have generated some best practices for successfully implementing new technology.



### Key Points

- Enterprise imaging strategies and tools are being widely adopted in many regions. Organisations with effective strategies are achieving positive outcomes today.
- While there are some positive Artificial Intelligence (AI) use cases being implemented in the imaging world, the uptake of the tools is slow, so AI will not have the impact it could on the imaging industry over the next 5 years.
- Digitised pathology processes are boosting efficiency and improving the quality of care. This technology will generate significant changes in the next 3 years and revolutionise the pathology industry over the next 15 years.
- To capitalise on imaging technology, organisations should create a comprehensive enterprise imaging strategy and get buy-in from all stakeholders, including department heads and clinicians.

Over the past 20 years, healthcare organisations all over the world have been investing in digital imaging solutions. As organisations in mature regions have digitised their various specialties, it has not been uncommon to select a different picture archiving and communication system (PACS) for each discipline, including radiology, cardiology, endoscopy, and more. This pattern creates a hodgepodge of eclectic solutions that are managed mostly at the departmental level.

Today, many clinicians in technologically advanced regions are ready to seek something better: consolidation. Organisations understandably want to reduce the number of imaging systems they use and the total amount they spend on imaging.

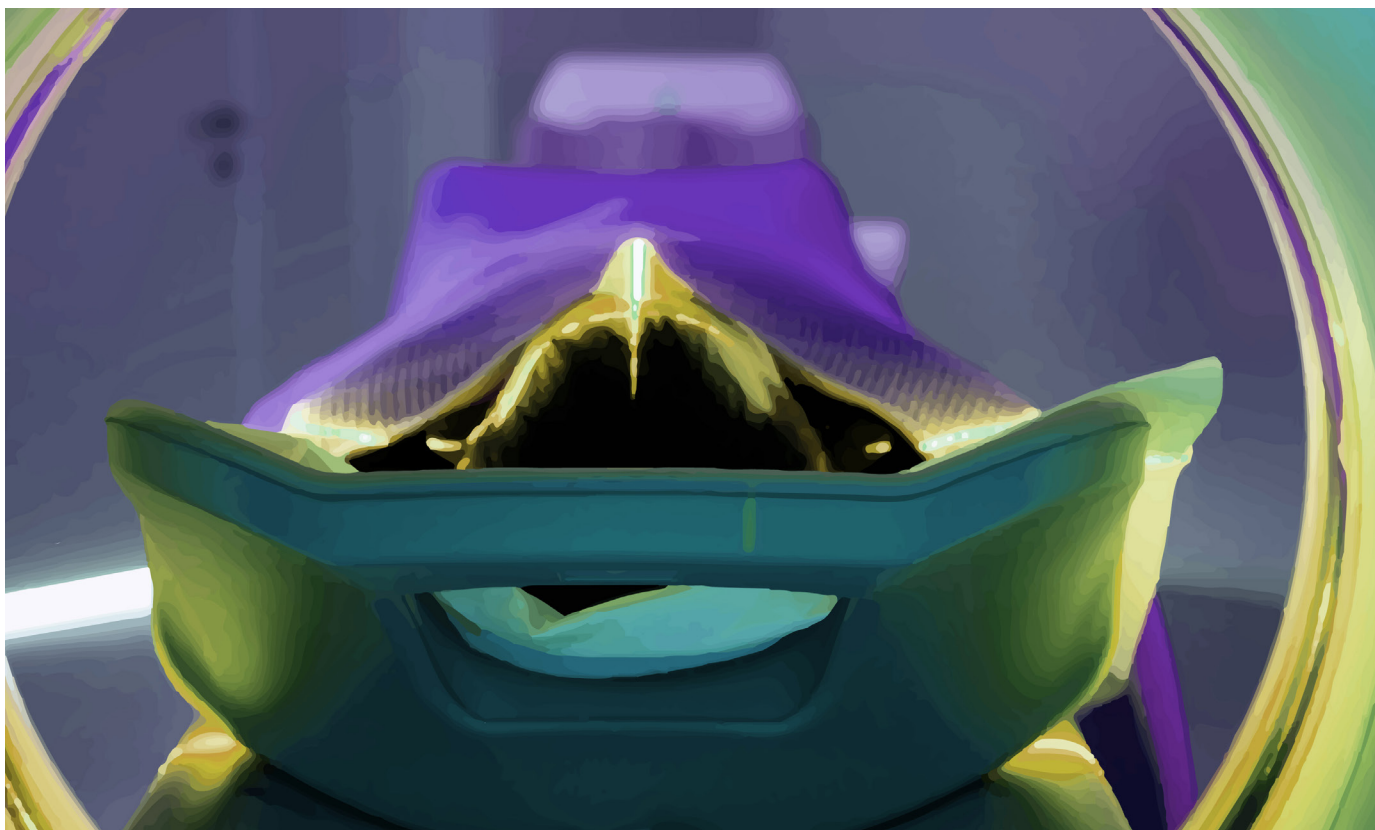
Ears are also perking up at talk of shiny, new tools such as artificial intelligence functionality. Many people are asking whether anyone is seeing positive outcomes from these solutions yet.

Luckily, the conversations my colleagues and I have with hundreds of healthcare stakeholders give us a decent idea of the status quo and what the near future will likely bring. Let's take a look at the exciting trends and opportunities in the world of digital imaging.

### EI, the VNA, and the Universal Viewer

Many healthcare leaders want a single imaging platform or solution that can aggregate and store all of their organisation's images across departments. It's equally important for their imaging technology to provide all physicians with the specialty-specific abilities and measurements that they need to be successful. Thus begin conversations about enterprise imaging, the vendor-neutral archive, and the universal viewer.

Enterprise imaging (EI) can be defined as "the ability to store and/or view images across the enterprise from more than one service line or storage solution" (Rasband &



Barton 2020). The vendor-neutral archive (VNA) provides the storage side, while a universal viewer can handle viewing.

Healthcare organisations in many regions—including the US, UK, Canada, Netherlands, Nordic regions, Southeast Asia, and Oceania—are acquiring VNA solutions quickly. In some parts of Canada and Europe, VNA decisions are being driven at a regional level. For example, a province in Canada might have only one PACS for the 100+ hospitals in the province. In addition, certain Nordic cities (such as Bergen and Stockholm) now host enormous archives in which to manage images for the entire region. The goal: to have a single source of truth with all patient-history data.

Overall, healthcare organisations are doing better at storing data in a single system than at viewing data in a single system. However, in the US, “[r]eported access to relevant images through both the VNA and universal viewer is up nearly 20% from 2018, with the most progress on the universal viewer side (primarily being used referentially). This shift is improving clinician productivity” (Rasband & Barton 2020). This progress will continue as healthcare leaders ask questions like, “What do we want to do with imaging in the long term? How can we improve our EI setup? What tools or changes are coming next?”

### Artificial Intelligence

Everyone is talking about healthcare artificial intelligence

(AI) tools, which KLAS Research defines as software that provides machine learning or natural language processing capabilities for healthcare-related clinical, operational, or financial areas” (Pretnik & Krotz 2019). Relatively few organisations are using AI in imaging yet. While there are a few use cases yielding positive outcomes (they will be discussed below), I don’t expect AI to be widespread in the imaging industry for at least five years. A number of significant barriers will probably keep progress slow.

One of these barriers is that some clinicians are hesitant to adopt tools that they fear will make clinicians obsolete. The truth is that AI technology isn’t advanced enough to do that, and it isn’t even designed to. The goal of most AI tools is to increase efficiency by doing some manual work for the clinicians, leaving those workers to do more of what they do best: think critically and interact with patients.

For example, certain vendors provide built-in triaging functions in their imaging tools. In a radiology PACS, such AI functionality can run algorithms on patient scans in the background, flag scans that show serious or urgent problems, and automatically shift those scans to the top of the radiologist’s queue. A radiologist can immediately be shown the scan of a patient with, say, a brain bleed, and get that patient to the hospital in time for life-saving treatment.

AI functionality can also improve the process of screening for breast cancer. The enormous numbers





of negative tests tend to create a constant backlog of images. However, an AI tool can quickly sift through the negatives and flag images that will need a closer look. Clinicians can then spend more time studying those cases and talking with patients. Before long, patients may even be able to hear by the end of an appointment if the results of the screening have been marked as negative.

As AI tools are refined and more widely adopted, they will facilitate advances in radiology, cardiology, precision medicine, and many other areas. The clinician experience, patient experience, and standard of care will all improve. Let's not stop talking about AI anytime soon. The more we normalise the usage of AI tools, the faster we can overcome its stigma and spur adoption.

### Digital Pathology

Pathology may not be considered "traditional" imaging, but it's an area ready to erupt in relevancy. Because of recent technological advances in image capturing, work-

a telepathology network. If a participating facility's pathologist is unavailable or needs a second opinion, the facility can now send a link to an expert elsewhere in the country. The expert can then click on the link to see the scan in real time and give input. That sure beats sending studies via the post or paying couriers.

Similarly, an Austrian clinician friend told me how elated their pathologists were to be able to attend multidisciplinary tumour board reviews electronically instead of driving four to eight hours each way to attend in person. These savings of time can equate to real savings in money.

With a projected shortage of pathologists, it's becoming critical to use pathologists' hours wisely. As digital functionality and algorithms relieve pathologists of manual tasks and travel, these pathologists can use their expertise to do more meaningful things, such as collaborating with and training each other, giving diagnoses, and arranging effective treatments.

There are still limitations in digital pathology tools, and

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## As AI tools are refined and more widely adopted, they will facilitate advances in radiology, cardiology, precision medicine, and many other areas

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flows, and AI, organisations in certain regions are starting to use digital pathology technology for primary diagnostic work, not just research. I think pathology will see dramatic changes in the next 2–5 years and be totally revolutionised in the next 15 years. It takes just a quick comparison of manual and digital methods to see why.

Most pathologists are still looking at slides under the microscope and then writing reports in their lab systems; a pathologist aided by digital tools can take images of a slide, scan them into the computer, and then manoeuvre and magnify those images effortlessly. Traditional measurement techniques involve special rulers and drawing on slides; in a pathology PACS, a pathologist can measure even curves or areas with just a few clicks. Manually counting each of a slide's mitotic cells takes ages; new AI technology can highlight the appropriate cells instantly.

These slick, new systems won't necessarily save smaller organisations money. However, current users testify of three main benefits: (1) improved quality of work, (2) improved efficiency, and (3) remote-reading capabilities (Lagemann & Christensen 2020). I will share a couple of specific examples.

Healthcare stakeholders in the Netherlands have set up

there are geographical, political, and legal barriers to overcome. However, the outcomes from early adopters are so momentous that I expect many of the barriers to be torn down swiftly. In fact, some softening of legal barriers has already happened as governing bodies have eased restrictions on the usage of digital pathology systems in response to COVID-19. This will further allow digital pathology tools to proliferate. At that point, it will be up to healthcare organisations to maximise the technology (and manage the enormous data burdens from pathology archives that can run in the petabytes or even exabytes) through effective strategising.

### Invest in an Imaging Strategy

About three years ago, I talked with a healthcare leader in the UK about their imaging tools. I learned that they had purchased a VNA and asked what they were doing with it. The response? "We haven't taken it out of the tin. Someone told us we should combine a VNA decision with our new PACS, but the VNA is now sitting on the shelf because we don't know what to do with it."

Many healthcare leaders move forward with a VNA, AI, or other decision without buy-in of enough departments and

clinicians. Some organisations waste the potential of their VNA by using it as backup storage for their radiology PACS. Others don't set up a governance structure and then wonder why their clinicians are confused or resistant.

Each of these situations leads to wasted resources and unhappy clinicians, and each can be prevented or corrected with a comprehensive EI strategy. Healthcare leaders should follow these best practices when outlining and executing a plan to take advantage of imaging technology:

- **Start early.** Begin discussing and planning long before any new tools arrive. If you have already implemented new tools and can see that your strategy is inadequate, regroup immediately to prevent further problems.

- **Put governance in place before purchasing any new tools.** Get input beforehand from every department so that the governance structures will be more likely to work and be supported. IT/PMO steering committees are particularly effective and produce the most outcomes (Rasband & Paxman 2018).

- **Understand the tools' capabilities and decide how you will use them.** Remember that a true EI setup will connect multiple service lines, consolidate everything into a single source, and provide specialty-specific functionality to each clinician.

- **Get all department heads on board.** It's okay if these leaders don't all agree with the specifics of the plan from day one, but they must at least understand and agree with an overall vision for EI before the organisation can move forward.

- **Create a realistic rollout timeline.** Decide the order in which new tools will be introduced and which departments will implement when. Start with the departments

most eager for change. This will give other department heads time to prepare.

- **Educate and include the clinicians.** They need to feel involved in the planning process and confident that they can be successful with the incoming tools. One Director of Pathology advised, "Take the time and money to let every pathologist do his or her own individual validation so that the pathologists will trust the system...We first introduced about 20 test cases for the pathologists to do both digitally and through the microscope so that they could note any differences" (Lagemann & Christensen 2020). Such efforts lead clinicians to embrace new tools.

- **Foster partnerships with your supplier(s).** Organisations that view their supplier as a strong partner report higher-than-average outcomes for their EI tools (Rasband & Paxman 2018).

### Warning: Progress Ahead

In a world of mind-boggling technology, it's good to see that healthcare imaging tools are finally starting to catch up. Seizing and managing new tools and methods will pose plenty of difficulties. However, as healthcare leaders follow IT pioneers by strategising wisely and implementing boldly, they will enhance the lives of clinicians and patients beyond recognition.

### About KLAS

KLAS is a healthcare IT-focused market research firm. Our mission is to improve the world's healthcare by amplifying the voice of providers and payers through data. KLAS provides transparent insights on the software and services that healthcare leaders use every day. ■

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# Role of Wearables in Combating COVID-19

Author: [João Bocas](#) | The Wearables Expert™ | Keynote Speaker | B2B Digital Influencer | Tech Entrepreneur | Digital Saludem Ltd | Brighton | UK

The current pandemic has highlighted the importance and usefulness of wearable medical devices during an infectious disease outbreak. An expert on wearables explains the benefits of the technology and urges all the stakeholders to implement it as soon as possible.

## Key Points

- In isolation, people resort to calling an ambulance if there is an emergency. This reactive system of care leads to unnecessary burden on hospitals.
- With wearable medical devices, this system can become much more efficient providing remote monitoring and timely medical care.
- The combination of wearables and AI will be the game changer in the healthcare sector allowing for handling big data and identifying trends and anomalies.
- The pandemic has stressed the urgent need to adopt wearable technologies as fast as possible. All stakeholders must embrace this as their priority.

Our lives have been disrupted like never before. Governments around the world have been advising us on measures such as social distancing, isolation, lockdown and quarantine. In seemingly every city, country and township around the world, people are closing up shop, keeping kids home from school, and keeping to themselves, all in the hope of minimising the spread of COVID-19. But what happens to us in isolation? How do we monitor and/or record our health and wellbeing efficiently and effectively when on our own?

### Using Wearable Devices to Measure Vital Signs

One of the problems that we are facing right now is that behind closed doors nobody knows what's happening to you. Then if something happens, the only option is to call an ambulance that comes with necessary equipment to take you to the nearest hospital.

It is the reactive healthcare system that we all know, perhaps the only system that most people know, including healthcare professionals, nurses, doctors and clinicians.

It is extremely costly, inefficient, and it is a kind of hit-and-miss approach, saving all those who are not too far off the mark with regards to their health. But it must be another way... most of you would argue.

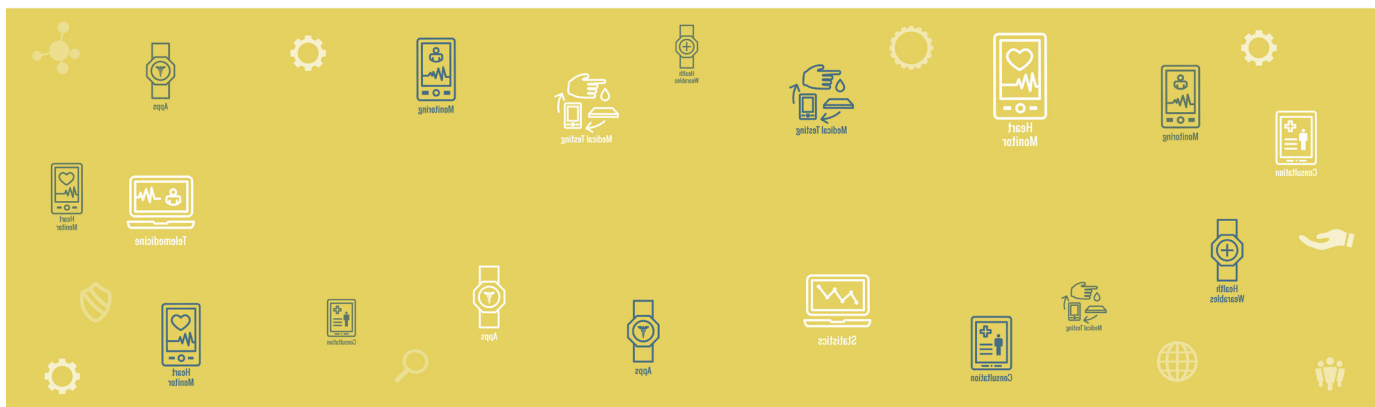
YES, there is – using wearable medical devices to measure, monitor, and continuously assess individuals and patients' health regularly and remotely. This is basically the term 'remote monitoring' that we hear so often amongst industry professionals, but that does not exist in the real world. Furthermore, the reactive (and old) approach is not scalable and just adds more and more pressure on health systems bringing more and more patients to hospitals and clinics.

However, there is hope, and the good news is that there are a handful of innovators with great wearable medical devices in the market. Especially in the last year, I witnessed several robust wrist device solutions that would make it possible to monitor the health of large quarantined populations, predicting the signs of potential illnesses early and sending medical care where it's needed most.

With COVID-19, the health and social care crisis was magnified to very large proportions due to the highly infectious and contagious characteristics of the coronavirus.

Tracking health metrics at home, e.g. by wearing an Apple Watch, has to be the way forward. Wearable devices now display better capabilities in terms of battery power, connectivity and even data accuracy.

I truly believe that the coronavirus has opened up a much



broader potential of wearable devices application and an opportunity to make the use case for adoption an easy task in the future.

Let me outline a scenario for you. Imagine ten thousand people under quarantine in one particular region. Each person has a wearable medical device on their wrist to get insights about their vital signs remotely. The device is continuously measuring the skin and body temperature, respiratory rate,

under observation, thanks to intelligent predictive AI, spotting problems before anyone dials 911 or even uses other methods, such as telemedicine.

In an ideal world, physicians don't have to be concerned and watch patient data until there is some kind of sophisticated and alarming alert. This is, in fact, my vision of the future and the true value of using wearable medical devices. Unlike traditional telemedicine, that in most cases still requires

## The reactive (and old) approach is not scalable and just adds more and more pressure on health systems bringing more and more patients to hospitals and clinics

pulse rate, heart rate and blood oxygen and, possibly, other health parameters. All of these health vital signs are directly correlated to COVID-19 – we could start triage, access and plan appropriate and targeted interventions early, and at the same time measure and mitigate health risks of spreading the virus by taking to the hospital only those requiring hospitalisation. This would prevent the spread of the disease and provide an early diagnosis for better outcomes – definitely a win-win for patients, healthcare workers and society at large.

### Wearables+AI: Game Changer in Healthcare

I have had this vision for a long time that the combination of wearables and artificial intelligence (AI) will be the true game changer in healthcare. In my book I have explored this vision further.

The acquired medical-grade health data is captured and retained in the cloud in order to instantly identify anomalies and trends. In this hypothetical scenario, any nurse or doctor could monitor the health metrics of ten thousand patients

one-by-one interactions, the wearable medical devices that I have mentioned would predict problems before they manifest themselves and automatically advise on immediate medical care interventions where those are most needed.

But why are we not doing this yet? Are we waiting for another global pandemic after COVID-19 to make this a reality?

Hopefully, COVID-19 passes by as soon as possible, and we all get back to normal. But I really wish that governments, health systems, healthcare providers and all stakeholders make utilisation of the technological capabilities available to us today their priority.

Using wearable medical devices in the health and care settings is a must, we cannot afford not to use them. Wearables are proven to be extremely efficient and could be a very powerful weapon that constitutes a perfect alliance for health results and the best possible delivery of sustainable healthcare of the future, that we all dream of and wish for. ■

# Influence of Biotin Nutritional Supplementation on Laboratory Testing: Sex and Gender Impact

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High dose biotin supplementation is most common among females and may cause faulty immunoassay results that delay diagnosis and treatment of serious medical conditions.

## Key Points

- Biotin, also known as Vitamin B7, is an essential micronutrient that widely functions in the metabolic processing of amino acids, fats, and carbohydrates.
- The use of biotin supplementation has been disproportionately reported by women.
- Interference of biotin on troponin testing may lead to underdiagnosis of cardiovascular disease that disproportionately affects women.
- Further education for patients in regards biased immunoassay results should take place to ensure prompt diagnosis and treatment of serious health conditions.

## Introduction

Evidence for the effects of biotin supplementation on laboratory testing has been increasingly identified as a possible source of bias between correlation of clinical symptoms and laboratory test values. The use of biotin supplementation has been disproportionately reported by women in the United States. There may be implications for women due to sex and gender differences in diagnosis and treatment of certain conditions that are managed based on the results of immunoassays which are adversely affected by high serum biotin concentrations.

## Biotin

Biotin, also known as Vitamin B7, is an essential micronutrient that widely functions in the metabolic processing of amino acids, fats, and carbohydrates. The daily

recommended dose of biotin for adults is 30 mcg which can be obtained from a regular, balanced diet. Signs of biotin deficiency include rashes, brittle nails, and loss of hair, and as such biotin supplementation has been marketed as a preventative measure for these conditions (Office of Dietary Supplements 2017). In the United States, 7.7% of adults self-reported the use of high dose biotin supplementation ranging from 1,000 to 50,000 mcg per day. Of this subset, 79.2% were women and 20.8% were men (Katzman et al. 2018).

Many widely used immunoassays utilise the biotin-streptavidin binding as a method of capturing the analyte. High serum concentrations of biotin can lead to assay interference (Gifford et al. 2019). Multiple assays, in particular high sensitivity troponin T (hs-TnT) and thyroid stimulating hormone (TSH), have been reportedly affected

Troponin T concentration, ng/L	Biotin concentration, µg/L			
	50	100	500	1000
18	25.4%	59.4% >	82.9%*,‡	> 82.9%*,‡
59	24.7%	55.8% >	94.8%*,‡	> 94.8%*,‡
201	21.6%	55.3%	96.4%‡	98.0%†,‡
6423	22.4%	52.8%	97.0%	98.5%
<b>Mean of biases</b>	23.5%	55.8%	96.7%	98.2%

Results are shown as negative biases in percentage before applying neutralisation protocol. Values below limit of blank were not taken into account for calculation of the mean of biases. \*Value below the limit of blank (3 ng/L). †Value below the limit of detection (5 ng/L). ‡Value below the 99th percentile (14 ng/L).

Table 1. Effect of biotin on troponin T concentrations measured by hs-cTnT assay. Source: [Schrapp et al. 2018](#).

at serum biotin levels above 20 ng/mL (Nguyen et al. 2020). The resultant interference has affected results of tests in the form of falsely elevated or decreased values. In conjunction with clinical symptomatology and exam findings, a trend of lab errors secondary to biotin interference has the potential to adversely impact the diagnosis and treatment of female patients due to higher rates of exogenous supplementation.

### Troponin

Cardiovascular disease is the leading cause of morbidity and mortality in both men and women in the United States. Traditionally viewed as a men's disease, cardiovascular disease is curiously more prevalent in women. While major risk factors like hypertension and diabetes affect both men and women, evidence suggests that female-specific risk factors, such as pregnancy and early menopause, exert significant influence on the impact of traditional risk factors on cardiovascular disease severity (Appelman et al. 2015). Sex based differences in clinical presentation of acute cardiac diseases, including myocardial infarction, have also been implicated as significant challenges to risk stratification. This has been most notably evident in female patients because they are more likely than men to present with atypical symptoms that may cause acute cardiovascular disease to be missed (Saeed et al. 2017). As such, women are prone to less aggressive treatment compared to their male counterparts for the similar clinical presentations.

As the diagnosis of acute cardiovascular disease depends on evidence of myocardial injury detected by hsTnT assays, interference of biotin on troponin testing may lead to an even further underdiagnosis of cardiovascular disease that

disproportionately affects women. In 2017, the FDA was notified about the death of a female patient who reported taking high dose biotin supplementation that died after a falsely low troponin level led to misdiagnosis. Her death was attributed to lab error secondary to biotin interference (Center for Devices and Radiological Health 2019). Serum biotin concentrations greater than 500 mcg/L have been linked to an over 95% decrease in troponin levels (Trambas et al. 2018). Interestingly, the quantitative troponin amount in a sample has been reported to not confer a direct correlation with the interference of biotin. Table 1 shows the initial absolute value of troponin demonstrating a mean negative bias that increases with higher levels of biotin, 23.5%, 55.8%, 96.7%, 98.2% at 50, 100, 500, 1000 mcg/L of biotin, respectively.

Of note, at the highest levels of biotin, 500 and 1000 mcg/L, the lower range of starting troponin levels of 18 and 59 mcg/L were reduced to the extent that a value to determine bias was unable to be recorded at the assay's 3 ng/L threshold for detection (Schrapp et al. 2018). Thus, it cannot be excluded that patients taking high dose biotin supplements presenting with clinically significant troponin elevations below 60 mcg/L may be missed on the initial assay. The negative bias of troponin levels with high dose biotin supplementation, combined with the already widely observed sex-based differences in acute cardiovascular disease presentations and risk stratification, further elucidates the need for a heightened clinical suspicion for patients whose laboratory test values do not correlate with the clinical presentation. The most at risk patients for this bias and potential undermanagement of acute cardiac disease are women.



## Thyroid Hormone

The rates of thyroid dysfunction between the sexes has been shown to be significantly different. In one study the prevalence of hyperthyroidism was 2.5% in females and 0.6% in males, and hypothyroidism 4.8% and 0.9% respectively (Bjoro et al. 2000). The onset of thyroid dysfunction is usually insidious. Before the introduction of modern laboratory testing, thyroid dysfunction was suggested by a number of clinical findings, including basal metabolic rate, heart rate, total serum cholesterol, reflex time, and creatinine kinase. A screening TSH is the single best test for thyroid dysfunction, supported by Free T3 and Free T4 (Garber et al. 2012). Interference threshold for TSH, Free T3 and Free T4 (x10<sup>3</sup> pg/mL) were 25, 70, and 100 respectively (Mrosewski et al. 2020). High dose biotin supplementation led to falsely high FT3 and FT4, and falsely low TSH (Trambas et al. 2018). Clinicians must be aware of the effects of biotin on immunoassays, and correlate test results with clinical evidence.

Of particular concern to women are the effects of thyroid dysfunction on the developing foetus during pregnancy. Children born to mothers with gestational hypothyroidism score significantly lower on numerous areas of neuropsychological testing, including intelligence, attention, reading ability, visual motor performance, and language. Maternal hyperthyroidism during gestation has been associated with an increased risk of spontaneous abortion, preterm delivery, low birth weight, and stillbirth. In addition to foetal complications, women with gestational hyperthyroidism are themselves at an increased risk for developing CHF, thyroid storm, and preeclampsia (Karassas et al. 2015). Prompt identification and treatment of these conditions during pregnancy is essential. Foetal cognitive deficits can develop in the first trimester if maternal hypothyroidism is inadequately managed.

Maternal thyrotoxicosis is treated most often with methimazole or propylthiouracil during the first three months of pregnancy, both of which are associated with teratogenic effects and make reliable laboratory diagnosis essential (Barbour 2017). The clinician that is aware of maternal biotin supplementation can improve identification and management of these conditions.

## Conclusion

The growing body of evidence suggesting biotin interference on numerous immunoassays further emphasises the importance of recognising sex-based differences in medical diagnosis and management. Nutritional supplements are becoming increasingly popular, but their regulation and indications are not yet widely accepted. Evidence that high dose biotin supplementation improves hair, skin, and nail growth is limited. We want to understate the fact that regular dietary and standard multivitamin amounts of biotin do not cause an elevation of biotin levels to the point that would cause interference with immunoassays or that there is any effect on pathophysiology of diseases. While some practitioners are privy to the possibility of erroneous low laboratory test results secondary to high dose biotin supplementation, it should be evident that further education for patients in regards biased immunoassay results should take place to ensure prompt diagnosis and treatment of serious health conditions (Bowen 2017). Our goal is to educate the medical community about the importance of documenting and reporting supplement use of patients to correlate with clinical presentation in the event of suspected lab error secondary to biotin interference.

## Conflict of Interest

None. ■

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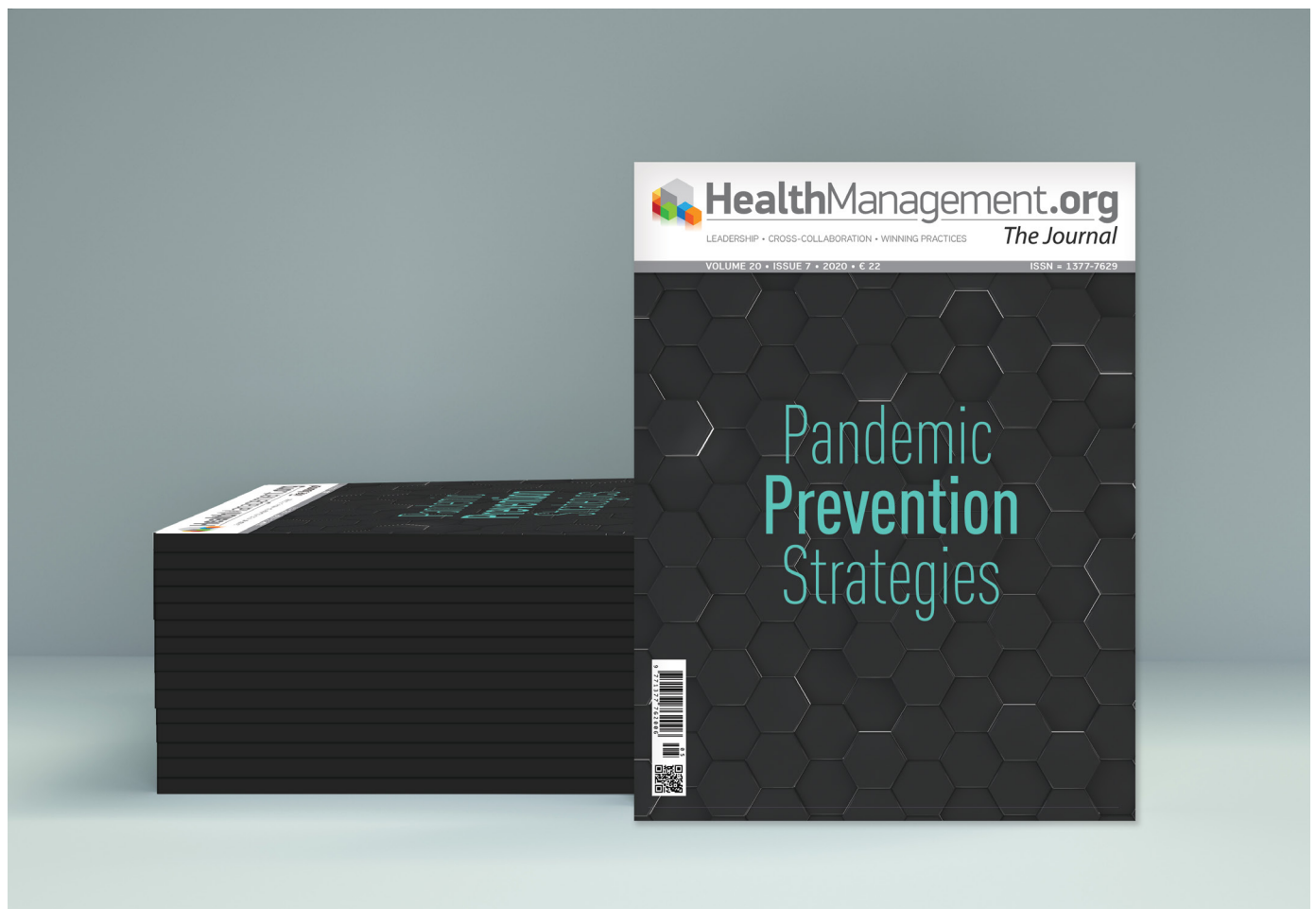
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