HTAi Virtual Conference, June 2021
Innovation through HTA

Panel Session Report

Making Room for Disruptive Innovation: Priorities, Agility and Efficiency?

Key points

The Covid-19 pandemic has created a synchronized sense of necessity to rapidly deploy innovations, requiring completely new agile approaches to determine priorities for health care provision and organisation, in a responsive, evidence-based and efficient manner. How can HTA learn from this to help health systems make room for disruptive innovations?

To free up resources for high-value innovations (many of which are high cost and disrupt the care pathway) and create the most efficient and effective healthcare system, all stakeholders need to commit to use of evidence and organisational change to optimize use of existing technologies.

In Australia, the review of all the 5,700 services in the Medical Benefits Schedule has relied on HTA principles and processes to understand not only what is high and low value care, but also the uncertainties. This has enabled development of clear guidance for optimal delivery of care in terms of referral procedures, practitioner delivery and treatment settings, assisted by fiscal incentives.

Health systems are complex and disjointed for individual patients to navigate to optimize their own care. Person-centered, value-based health care can be developed to improve population outcomes and equity to access of care, but this requires structured and systematic involvement of all stakeholders, particularly patients.

Human factors contribute to the inefficiencies in a health system, so the best evidence about optimal practice needs to be presented in new and informative ways to all stakeholders, alongside mechanisms to support behaviour change.

Many collaborative projects have developed tools to support patient involvement in medicines development and HTA. These need to be promulgated and developed for other areas such as health system organisation.

At the conclusion of the meeting, the audience believed that to make room for disruptive innovation, stakeholders need to be involved in the life cycle of the technology development and evaluation, and holistic frameworks need to be used to determine the value of innovation throughout the full diffusion curve.

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Glossary

EPF	European Patients' Forum
EU	European Union
EUPATI	European Patients Academy for Therapeutic Innovation
H_2O	Health Outcomes Observatory
HTA	Health Technology Assessment
HTAi	Health Technology Assessment international
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PCIG	HTAi Interest Group for Patient and Citizen Involvement in HTA
PFMD	Patient Focused Medicines Development

About HTAi
Health Technology Assessment international (HTAi) is the global scientific and professional society for all those who produce, use, or encounter HTA. HTAi has members from over 65 countries and embraces all stakeholders, including researchers, agencies, policy makers, industry, academia, health service providers, and patients/consumers. HTAi is the neutral forum for collaboration and the sharing of leading information and expertise. This panel was judged by three reviewers and selected for presentation at the 2021 annual meeting by the International Scientific Program Committee.

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Making Room for Disruptive Innovation in the Horizon: Priorities, Agility and Efficiency for All?

1. Introduction

Dr Alicia Granados, Head Global HTA Strategy, Sanofi

Drawing on her experience as a leader in HTA bodies, the Spanish health system and now industry, Dr Granados introduced this HTAi 2021 panel exploring how space can be made in health systems for disruptive, radical innovations.

The Covid-19 pandemic is humanitarian and socioeconomic crisis that has impacted lives. It has shown a synchronized sense of necessity, revealing new uncertainties, affecting evidence generation and interpretation, and impacting HTA. Inequalities have been obvious and ethical debate has been ignited among the public about the value of a life.

To address the challenges posed by the pandemic, health care systems and life sciences companies have been called upon to be responsive in new and disruptive ways "thinking outside the box". True innovation has occurred in many areas, and on reflection success factors have been identified as the ability to set *priorities* and the *efficiency* and *agility* of interconnected systems. What do these factors (alone and in combination) teach us about building a sustainable and resilient health system that might help make room for future innovations?

For HTA in particular, we need to consider if we can learn from these experiences and perhaps innovate to HTA 3.0, considering:

- priorities - for the health system, or HTA?
- efficiency – for what proportion of health care expenses – all services or just medicines[1]?
- agility – what does it mean, particularly for patients?

Before turning to the panellists to consider these issues, the audience were asked a question.

Poll question with audience
How does HTA need to innovate – priorities, efficiency, agility?

35%	identifying high and low value healthcare beyond the medicines
35%	involving and engaging other stakeholders in HTA and science
24%	priorities congruent with healthcare priorities
6%	implementing iterative and holistic value frameworks beyond the cost-effectiveness threshold
0%	HTA specialisation in therapeutic areas.

[1] traditionally HTA has focussed on medicines, which is less than 20% of the health care budget, but is this the most cost-effective use of HTA?

2. The Art of Persuasion: Optimal Practice in Healthcare – A Brief Policy Perspective

Sir Andrew Dillon, Visiting Professor, Institute for Global Health Innovation, Imperial College London, UK

Sir Andrew Dillon reflected on the need for optimal practice in healthcare and how evidence-informed guidance can help set priorities and release resources for innovation.

All health systems face many challenges as they emerge from the pandemic. There is a question about the extent to which these can be addressed by the health system improving the way it sets priorities, becoming more agile in the organisation and delivery of services and driving efficiencies.

It is standard practice for HTA to evaluate manufactured technologies such as medicines, devices, diagnostics and digital health technologies, but that is only a minority of the total cost of the health system. In most health care systems, the majority of costs relate to staff and fixed assets such as buildings and equipment, areas that conventionally HTA has not addressed. In order to free up resources for innovation and disruptive health technologies, there is a need to review how all of these resources are used, which suggests that it may be appropriate to consider a wider definition of "interventions" (rather than just technologies) that takes account of a wider definition of costs.

Decision-makers at all levels need to be persuaded to commit to identifying and following optimal practice through evidence-informed protocols and guidelines, some of which will come from HTA. These protocols and guidelines need to be developed taking account of the priorities, values and preferences of the health system and the patients they serve.

From a policy perspective, health systems and their patients require clinical decision-making that optimises outcomes and use of resources. Patients want what works for them, but it is in their interests that the health system is organised to optimize use of resources. If it does not, health gain at a population level will be compromised. There is a need to avoid interventions that have little or no value and deploy interventions that work where they have most impact. Health systems need to actively incentivise optimal practice and disincentivise the use of low value interventions.

Evidence is essential in revealing optimal practice and determining priorities. The tools and techniques used in HTA are an essential, though not sufficient resource. Decision-makers need to deploy HTA as part of a decision framework, which takes account of the values, preferences and priorities of all the health system's beneficiaries.

Optimal practice may have a compelling logic, but in practice there are significant barriers that sometimes makes it difficult to put in place. This is the case, even in health systems where there is a tradition of using evidence, good organisation, plentiful resources and well-trained staff who are committed to doing a good job. Barriers to optimal practice include:

- *The absence of a sufficiently compelling narrative* about the potential to improve outcomes and the opportunity to free up space for innovation, by disinvesting in low value treatments and optimal use of effective interventions.
  It is understandable that there is enthusiasm to try new interventions, rather than examining your existing practice. However, this means that much of the argument about providing rapid patient access to innovation has focussed on the need for additional money and resources, rather than evaluating opportunities to free up resources before you ask for more.

- There is *variable awareness of the evidence against the use of low value interventions, and the evidence in favour of the higher value alternatives* (including for example, watchful waiting or best supportive care in some cases).
  This can be true even when there is pressure from a health system to optimize practice, when evidence is used frequently, or when there are substantial financial pressures (where it may be anticipated that the system would be looking for opportunities to avoid using low value interventions and focus their resources on interventions that really have an effect).
- *Health system fiscal incentives promote low value care by rewarding clinicians for undertaking interventions that do not improve patient outcomes*. This is often driven by health system and patient expectations that can be hard to oppose.
- The *perception that driving out low value practice is less important than the uptake of new interventions*. However, the former should be a pre-cursor to the latter.
- *Inertia.* It can be difficult to shift from familiar and comfortable practice to different (better) practice.

The national health service (NHS) in England has been on a voyage of discovery over many years to reach a position where it can be confident that everything it offers to patients is an appropriate balance between what services cost and patient outcomes. This began with clinical professionals and their professional associations developing evidence-based guidelines. The government has always had an important role to play through the way it structures the NHS and its research programmes. Externally, the Cochrane collaboration, which was established in the UK in 1993, has always sought to identify the best evidence to inform clinical practice about what works, what doesn't work or what only works in a particular context. Since 1999, NICE has assembled a library of evidence-based guidance in the form of clinical guidelines, technology appraisals and cost saving recommendations. All aim to encourage optimal practice in the health care system, avoiding adoption of new technologies that do not demonstrate sufficient value to patients for the cost they are incurring and encouraging use of technologies demonstrated to be of value. New collaborations have recently emerged, such as the Academy of Medical Royal Colleges (in conjunction with NICE and NHS England), which developed the Evidence-Based Interventions Programme in 2020[2] to prevent avoidable harm to patients, avoid unnecessary operations and to free up clinical time by only offering interventions on the NHS that are evidence-based and appropriate.

How do we persuade health professionals to change their practice? For health professionals and patients, evidence is essential, and the starting point. HTA can help sift, sort and order use of healthcare interventions to design optimal care pathways that promote the most effective new interventions, avoid the adoption of new technologies that offer little incremental benefit and demote low value practice. Beyond evidence, health system funders need to develop and promote clinical and business cases to persuade stakeholders of the importance of driving out low value interventions and promoting interventions that work. This can be achieved through organisational structures that reduce or eliminate fiscal incentives for sub-optimal practice. Professional associations can use their networks and credibility to promote optimal practice. Patient groups should advocate for what works and adds value, and improves outcomes for the entire patient community.

If we are going to make room for exciting new innovations, many of which are high cost and disrupt the care pathway, there needs to be a commitment to optimize the technologies that are currently available. This will enable health systems to operate in an agile and efficient way and do the best for the patients they are serving.

[2] aomrcebi – Evidence-based interventions

3. Precision Policy - HTA Supporting Health System Efficiency: Select Examples from Australia

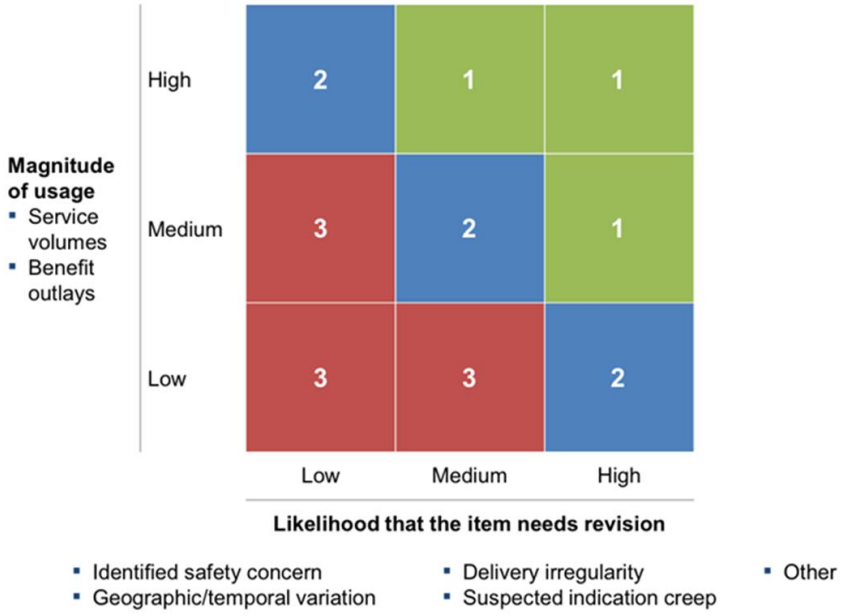
Professor Adam Elshaug, Professor in Health Policy, and Director Centre for Health Policy, Melbourne School of Population and Global Health and Melbourne Medical School, The University of Melbourne; Member Medicare Benefits Schedule Review Taskforce, Australia

Professor Elshaug presented the approach of *Precision Policy*[3] to identify low value care in health systems and drive appropriate delivery of services that could free up resources for other health service investment.

Similar to other countries, Australia has good HTA processes for assessing new health technologies. However, in 2007, we conducted research that identified challenges in Australian policy processes for assessing disinvestment from low-value health care practices[4]. In 2015, I was invited to be a member of a governmental taskforce to review Australia's Medicare Benefits Schedule. This work involved approximately 200 discipline-specific clinical committees and working groups, engaging more than 700 clinicians, health sector and consumer (health system beneficiary/patient) experts. The entire lens of the review was intended to be through the patients' eyes and so in addition there was a standalone consumer representative committee. Over five years it reviewed all 5,700 fee-for-service items (non-pharmaceutical interventions) on the schedule. The final report made over 1,400 recommendations to government relating to micro (individual item) and meso level (payment model) reforms[5].

HTA was fundamental to the process, but in many ways it was unrecognizable as traditional HTA. The process began with a prioritization exercise to identify priorities for review using the matrix presented in Figure 1.

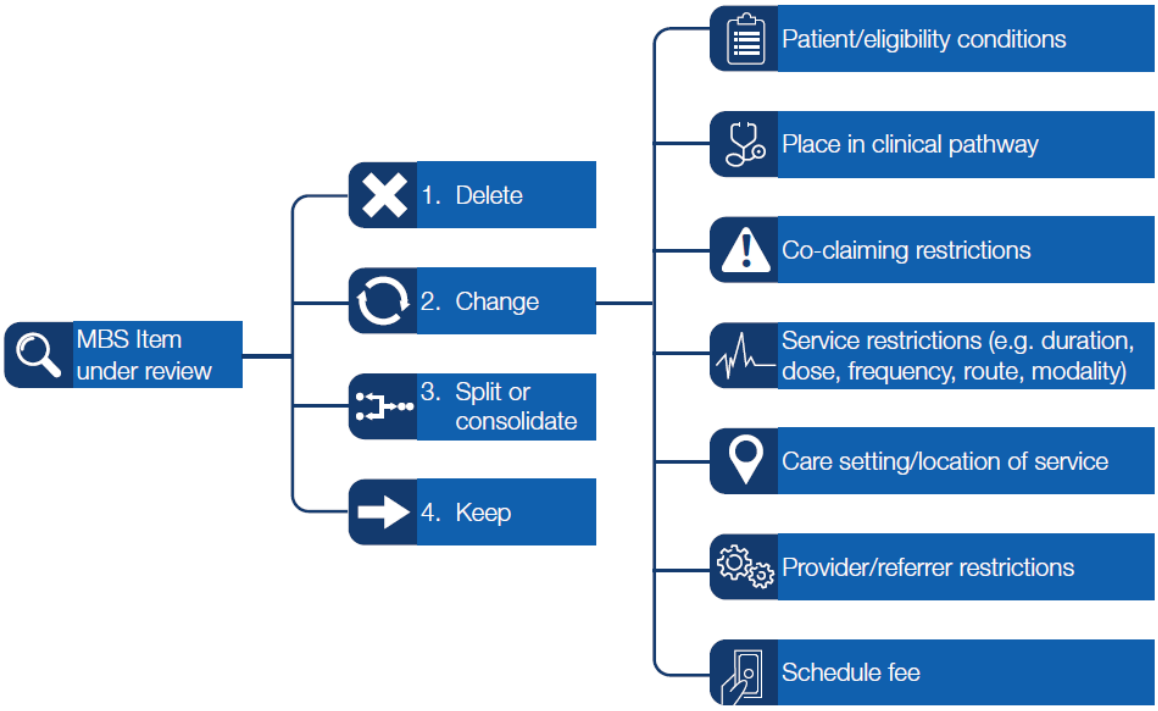
Figure 1. Prioritization matrix for revision of Australian Medicare Benefits Schedule items



[3] Trademark/patent pending
[4] https://pubmed.ncbi.nlm.nih.gov/17973993/
[5] https://www.health.gov.au/resources/publications/medicare-benefits-schedule-review-taskforce-final-report

Then each of the 5,7000 items was reviewed and a range of recommendations were possible, as outlined in Figure 2. This process was fully documented in over 80 public reports, available on the website.

Figure 2. Types of item level recommendations with recommendations for change in Australia's Medicare Benefits Schedule



Often the sub-optimal care issues identified did not relate to availability of evidence, but implementation to ensure appropriate use. This is where HTA made an important contribution, elucidating that decisions about health technologies are not dichotomous recommendations of "valuable" or "useless", but that there is a spectrum. There is appropriate use, heterogeneity of treatment effect, and a need to identify high value vs low value applications, and where the grey zone of uncertainty might lie. Identification of this fundamental aspect led to the development of the *Precision Policy* concept to drive efficiencies in the healthcare system.

Two cases in the review provide examples of the nuanced issues addressed.

Example 1. Laboratory or home-based sleep studies for sleep apnoea

The first example required the *Precision Policy* approach and related to two ways of providing a sleep study to diagnose sleep apnoea. A laboratory-based approach has a fee of $606.35, whereas the in-home-based item has a fee of $345.75. The form of test should be decided on the basis an individual's likelihood of having moderate to severe sleep apnoea as determined by accepted clinical scales, with more severe cases being sent to the laboratory.

HTA has provided the evidence and rationale for sleep studies, articulating how to allocate patients to home or in-laboratory according to pre-test probability of severity of condition. However, in practice this guidance was not being followed. Forty percent of physicians only conducted home-based studies, whilst 40% only conducted laboratory-based studies,

leaving just 20% of physicians who offered both services. So, allocation depended which physician patients were referred to by their general practitioner.

To resolve this issue, the indications for appropriate use according to the pre-test probability were refined. Clinicians were required to document appropriate triage to laboratory or home-based testing and these rules were codified and payment was contingent upon this.

After application of these changes there was an immediate 20% reduction in all forms of sleep studies across Australia[6], thus clearly delivering a major efficiency overall. In terms of the form of sleep study, there was an inversion in the use of laboratory to home services from 1.05 to 0.85. More people were given home-based tests, which were cheaper and more appropriate setting for patients.

From just these few service items, savings of 10s of millions of dollars per year were achieved that could be reinvested into other services. This small part of the review would have been sufficient to fund the entire 5-year Medical Benefits Schedule review process.

Example 2. Spinal x-rays

This example did not require *Precision Policy* approach, but was more of a "blunt" policy intervention relating to use of x-rays. Up to the point of the policy intervention in November 2017, there were 15,000-20,000 3 and 4-region spinal x-rays undertaken per month. These could be requested by medical practitioners, chiropractors, physiotherapists, or osteopaths. After the policy intervention, chiropractors lost the ability to request these x-rays and the number reduced to a few hundred per month, delivering major savings.

Measuring low value care

The Evidence-Based Interventions committee in the UK has started to do similar work reviewing individual services. It has taken account of our work in Australia and elsewhere and produced its second engagement document in July 2020.

In Australia, we have developed dashboards that can present variation in use of low value services within a healthcare system (e.g., hospital) and across all healthcare systems. Alternatively, the dashboard can present information by a particular medical service and plot variation across systems. This information is being fed back to clinicians who are now beginning to change their practice.

The Covid-19 pandemic has generated natural experiments about low value care in many health systems. In Australia, there was a dramatic decrease in elective procedures and so we hypothesize that this has led to a reduction in low value care. Work is now underway to ensure that those low value procedures do not restart after the pandemic.

[6] This evaluation was undertaken prior to March 2020 and so is not affected by any service disruption to the Covid-19 pandemic.

4. Healthcare Agility (or lack of): Impact on Patients' Outcomes?

Nicola Bedlington, Special Advisor, European Patients' Forum

Nicola Bedlington reflected on the need for healthcare agility to improve patients' outcomes, drawing on the range of work undertaken by the European Patient's Forum (EPF), which brings together more than 75 European umbrella patient organisations.

The Covid-19 pandemic has created a health, humanitarian and economic crisis, which has disproportionately affected patients living with chronic diseases. EPF undertook a survey in September-October 2020 to understand the impact of the pandemic on patients[7]. Of the 125 respondents, 46% were patient organisations and 54% were individual patients or carers. Ninety-five percent of the respondents indicated one or more challenges (65% increased stress/anxiety, 56% social isolation, 49% treatment delay, 37% lack of communication from national organisations and healthcare professionals), with 56% highlighting concerns about continued and timely access to treatment.

Of the survey respondents, 69% reported issues accessing healthcare (44% accessing appointment with specialist, 33% reduced sense of safety when visiting healthcare professionals, 23% accessing appointment with primary care doctor, 21% accessing medicines, 19% accessing surgery). Patient organizations felt that the most important issues for national governments to focus on were alternative solutions to access treatments (50%), securing access to effective and safe Covid-19 vaccines (44%), providing accessible Covid-19 testing framework and facilities (44%), investing and improving healthcare capacity (38%).

The survey identified that these significant impacts experienced by patients resulted from weaknesses in the system that existed previously, but were exacerbated during the pandemic.

Patients are calling for an efficient, agile and resilient healthcare system, but who should be agile? Is it the patients or the healthcare system?

A case study of one haemophilia expert patient in the Netherlands who has multi-morbidities puts this into perspective. This patient engages with 14 healthcare professionals to manage his care (haematologist, haemophilia nurse, infectious diseases nurse and specialists (to manage transfusion acquired HIV and HCV), social work, cardiologist, orthopedic surgeon, rehabilitation doctor, specialist and local pharmacist, general practitioner, physiotherapies, nephrologist and dietician). He needs to be agile and health literate to navigate this highly complex system, where primary and secondary care services often work in silos and integrated care is not a reality.

If patients could be effectively involved in health service organisation to share their real-world experiences this could help strengthen and improve the system and its agility.

In general, the health system is not as patient-centred as it could be.

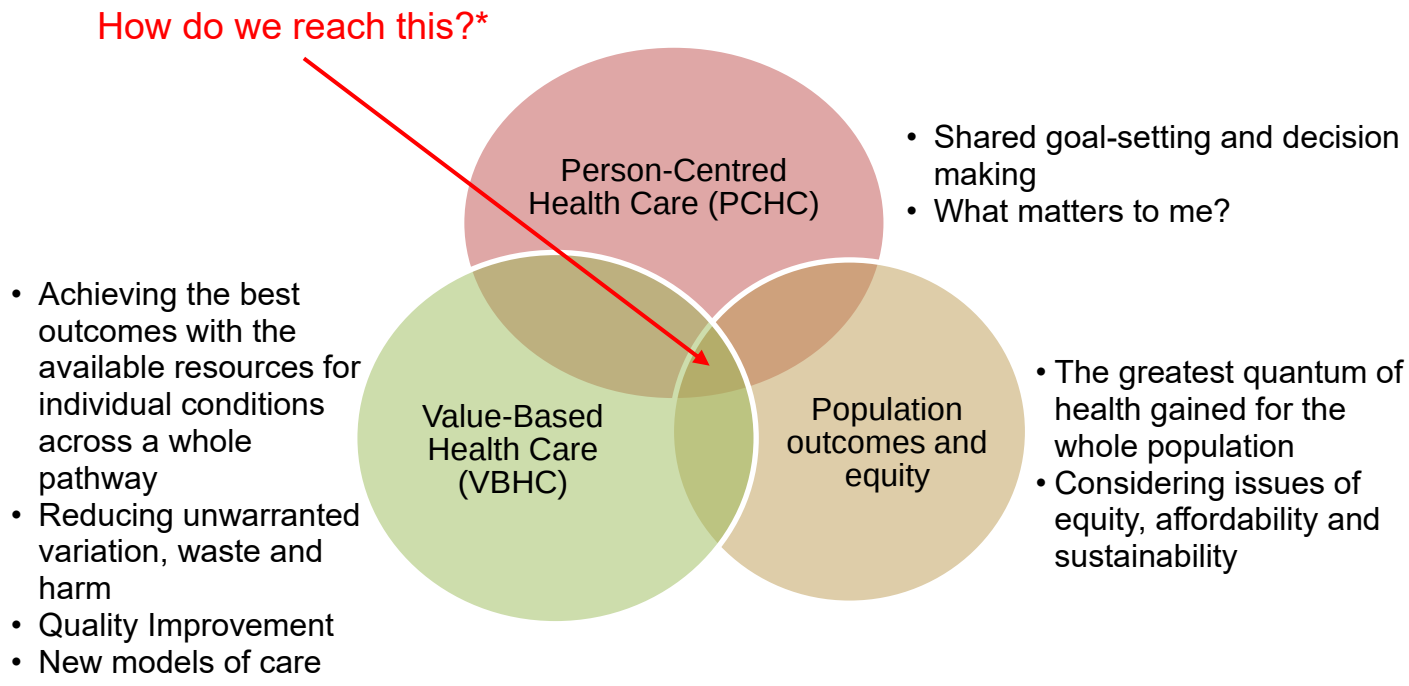
- The information provided to patients does not always fulfil their needs (e.g., the Patient Information Leaflet that accompanies a new medicine), or is not available (unpublished results of clinical trials).
- Communication with healthcare professions is not always easy due to time constraints, poor communication skills, medical culture etc.

[7] Survey Report on the Impact of the COVID-19 Pandemic on Patients & Patient Organisations (eu-patient.eu)

- Equity of access to even the most basic aspects of healthcare (from diagnosis to disease management) remains a big issue across countries in Europe and inequalities within countries.
- Innovations are developed and evaluated without meaningful patient involvement over the life cycle of development (particularly for non-medicines technologies).

Work that Nicola co-leads, with Dr Sally Lewis, is advising how to consider value in an integrated healthcare system combining the concepts of value-based healthcare and person-centred health care, taking account of population outcomes/equity. This project aims to find the sweet spot where all these aspects combine as outlined in Figure 3. The research report, launched in September 2021, should inform the discussion about how different stakeholders could be involved in an agile manner to set priorities and improve the efficiency of the health system, making room for disruptive innovations.

Figure 3. Value in an Integrated Healthcare System
(Courtesy of Dr Sally Lewis, National Clinical Lead for Value-Based and Prudent Health Care, Wales)



The Covid-19 pandemic has accelerated the digitization of healthcare and the EU has several policy initiatives underway relating to digital health and health data infrastructures. In relation to HTA, there are two different aspects. Digital health tools could be a valuable tool to collect data to inform HTA. Digital health solutions would benefit from HTA. However, there are challenges as this is a fast evolving, fragmented and complex sector. Furthermore, there is a paucity of patient involvement in horizon scanning for the most important digital health developments and involvement in their evaluation. Consequently, EPF is organizing a congress in October to discuss issues related to the digital transformation of healthcare.

After many years of discussion, a compromise has been agreed and the legislation to support HTA collaboration across the EU has been agreed (June 2021). Patient organisations support this collaboration, but in developing the recent consensus there are questions about whether the learnings from Covid-19 have been taken on board. For example, taking account of conversations like this about the use of HTA in the wider health system context. Another issue is meaningful patient involvement. Although there are opportunities for patient involvement in the activities of the new EU HTA collaboration, patient groups are disappointed that patient representatives are not involved in the governance. As the EU HTA collaboration is implemented in the coming years, it will be vital to consider new learnings and ensure meaningful patient involvement.

EPF is a partner in a new Innovative Medicines Initiative project – Health Outcomes Observatory (H_2O). Patient-centric pan-European and national observatories will be established that engage patients and connect providers, equipping them with the necessary data to improve patient care. Based on transparency and trust, they aim to build a community of patient-centric and outcomes-driven organizations that become a vibrant learning community. Through this work they hope to change mindsets and behaviours towards adoption of value-based health care and patient empowerment, thus driving culture change and hopefully overcoming some of the lack of inertia that Andrew discussed.

This is just one of the many initiatives underway in Europe that might offer insights about how to make room for disruptive innovation. However, there are still questions about how we collaborate, ensure synergies, not duplication, and identify how each stakeholder can best be involved to develop more efficient, agile and resilient health systems.

5. Discussion

Dr Granados thanked the panelists for thinking outside the traditional box of HTA to consider how we can make room for disruptive innovation, and turned to audience for questions.

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Stella O'Brien, NICE Public Partner, England: I am quite troubled by the number of good health and social care reports that provide clear, relevant recommendations.
Everyone agrees on the need for their timely implementation, so what is the inertia that stops necessary reform?
Is disruption the only way ahead, what about reformation?

AD: We could have been having a conversation like this 20 years ago. That said, there has been major progress in the knowledge base for moving to optimal practice. The problem is that one solution cannot be applied in all health care systems. Even within health systems, some parts perform well and some professional groups are more committed to an evidence-based approach. This reality will always be there. This is partly because health systems are organised by humans, not machines, so the full range of human frailties come to play, and the system will not perform optimally all the time.

However, as the other speakers highlighted, constant pressure is needed to renew dialogue among stakeholders and drive change. We need patients to be engaged in health system organisation. We need to look for new ways at a micro, meso and macro level to stimulate and incentivize health systems, like they are doing in Australia, developing bespoke tools that can confront clinical decision makers with the reality of what they are doing and providing the opportunity for them to do better. Unless we continue to do that there will be atrophy. I don't think we'll get to the point where we are completely confident that everyone is doing the right thing all the time, but this conversation needs to be ongoing and the initiatives we have heard about need to continue to drive reformation as Stella highlights.

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Unknown questioner: Do you think health services and HTA agencies across the world are ready to embrace patient-centredness as a key aspect of future optimal systems? If not, why not? And what needs to happen to make progress towards patient-centred health systems?

NB: It is often one step forward, two steps back.

Leaders who champion patient-centredness underline that patient-centredness and patient involvement is not just a good thing to do, but that it is a strategic and business imperative. In some environments this mindset is less apparent. This is not necessarily due to the socio-economic situation of a country or a particular context. So, leadership and leading by example is key.

Patient involvement should occur from the onset of an activity, not just at the end to rubber stamp a decision. Learning could be taken from some of the EU projects. They show that the methodology, approach and evaluation of each patient involvement activity needs to be considered to understand how effective the input was and how it can be improved. This needs to be addressed at all levels – political, policy, programme and project.

There has been much progress in patient involvement over the life cycle of medicines from research prioritization to collection of real-world evidence. It would be nice to see similar progress in patient involvement in design, application and evaluation of digital health tools and design and improvement of health services. That requires major efforts in collaboration and trust. Patient-centredness is a journey and we are moving in the right direction.

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AG: In the opening poll question, no one thought that there was a need for HTA specialization. Let's discuss this.

AG: There are a lot of groups all over the world evaluating the same health interventions. When new and advanced scientific approaches are used to develop innovative therapies, there are few experts available, so would specialization of HTA be a way forward? For example, could some HTA groups specialize in, for example, HTA of cancer or rare disease treatments? Could this contribute to agility or efficiency?

AD: When we have more than 50 HTA bodies assessing complex information to determine the additional benefit of the latest health technology, this could be an argument to support efficiency. This has been debated for many years in the EU and even in the UK we have two or three different HTA bodies looking at the same health technologies. One of the difficulties is that (depending on how you define the boundaries of HTA, and where health system decision-making happens) there are legitimate differences in the conclusions that health care systems reach about the value of new health technologies and the nature of what is optimal practice. These arise due to different priorities, patients' expectations, clinical practice culture and the relative wealth of the health care system. These all affect the decisions about whether to use a technology or deploy it in a certain way. For me, it's better to focus on standardizing methodologies. If standard methodologies are used in different health care systems and they come to different conclusions you can have confidence that they have used appropriate methods to understand the science, but that their interpretation for local practice is different.

AE: One of the limitations of the review of Australian Medical Benefits Schedule was that it was undertaken specialty by specialty (e.g., cardiology). This lacked a cross-system view, meaning that other potential treatment options outside the specialty were ignored. So, it is important to think about whether you consider services for particular specialties or diseases as a whole. This could be the next step for the Australian review.

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AG: Neil Bertelsen, past Chair of the HTAi Interest Group for Patient and Citizen Involvement in HTA (PCIG), gave an impactful keynote presentation prior to the plenary session on Patients at the Heart of Innovation in this conference (it can be viewed here). Learning from the two pandemics of HIV and Covid-19, he stressed that patients are the solution not the problem, which is a sentiment I agree with. The question is how can we make patients the solution?

NB: Patient involvement needs to be seen as an investment, investing resources in ensuring systematic, structured patient involvement. That requires awareness raising and specific education. Firstly, with patients to enable them to be fully equipped to contribute as an equal in discussions drawing on their unique experiential knowledge and expertise. Secondly raising awareness with other stakeholders, to understand how to engage patients effectively.

A multitude of useful projects have addressed these issues. The European Patient Academy on Therapeutic Innovation (EUPATI) has a specific module on HTA, which was reviewed by experts in HTAi and they contribute to EUPATI training activities. The Paradigm project considered patient involvement through the medicine's life cycle. This was the first Innovative Medicines Initiative project that HTAi was involved in. PCIG, under the leadership of Neil Bertelsen, was seen as a trusted broker to bring together HTA bodies and develop a comprehensive toolkit to support patient involvement in Early Dialogues designed for HTA bodies – thus raising their awareness. PCIG has also developed a range of tools to support patient involvement in HTA and these are available on the HTAi website.

Another important aspect is to consider metrics of patient involvement. A tool has been developed that measures the return on investment in patient involvement, which supports review and improvement of involvement activities.

There are lots of tools and resources available to systemize and structure patient involvement in HTA, the challenge is how to bring them together coherently and avoid duplication. In this regard, the Patient Focused Medicines Development (PFMD) initiative is a global platform hosting state of the art patient involvement tools, and HTAi is involved in this work.

At an EU level, I think there is political will to support patient involvement. What is needed now are processes to enable the uptake, implementation and review of effective patient involvement.

AD: I agree that patients are not the problem. However, I am not sure that patients are the solution, because if patients are the solution, you need to ask what the problem is. Patients are the point and the reason why innovators are developing new treatments and why people work in health care systems. People's health needs to be supported or ill health treated.

When NICE was set up in 1999, it had a clear mandate to involve patients and they have informed both NICE methods in general and recommendations about individual health technologies. The patient involvement processes used by NICE have evolved over time as experience has accumulated and feedback has been received from both the patients and representatives involved and committee members making the recommendations.

Given the high level academic and clinical expertise of appraisal committees and the complexity of evidence they consider, it can be challenging and intimidating for anyone outside the committee to contribute and this is a particular concern for patient representatives. Unless you are trained and work in the field and you understand the language being used, it is extraordinarily difficult. One of the things we may want to consider is whether a syllabus could be prepared to support people who want to get involved in health

system decision making. Rather than putting a patient directly into this setting with no support to tick the box of patient involvement, we could help train and support them to engage more effectively.

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Professor Robyn Ward, Chair Commonwealth Medical Services Advisory Committee, Australia: Is low value care really decreasing – can we make system wide changes based on data?

AE: In Australia the low-value care analyses and dashboards are being run across four states, and covering about 70% of the privately insured population. Analyses clearly demonstrate that there have been reductions in low value care.

Robyn Ward: If we seek to divert doctor's activities away from one low value area, won't they just increase their income, by providing a different medical service, which might be equally low value?

AE: As it is clear that doctors want to maintain their income that can happen and we are now monitoring these "substitution effects". However, it doesn't always happen, because doctors have the opportunity to address unmet needs or areas where there is underuse of higher value services. This an important part of changing the overall mix of practice and services.

The other aspect this highlights is the issue of supply-driven demand. When health systems see low value care being provided, they recognise that they may have an over-supply of doctors in a certain area and an under-supply in another area. So, this process can be used to redistribute the work force to meet the needs of the population. In Australia, state systems have taken this as an opportunity to rethink supply-capacity and distribution.

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To conclude the discussion, the poll question with the audience was repeated. This identified that involving and engaging other stakeholders in HTA and science was now the key priority, followed by implementing iterative and holistic value frameworks beyond the cost-effectiveness threshold.

AG concluded that this panel has shown the work underway to use HTA and evidence to disinvest from low-value technologies and sub-optimal practice and to support person-centred value-based healthcare. Furthermore, the pandemic has shown that HTA must be agile and responsive to changing health systems and policy imperatives.

At the EUnetHTA Forum in 2014, the term HTA 2.0 was used to describe the step change in collaboration in HTA across national borders, with a new intensity and coherence, engaging stakeholders in some elements and working with regulators. The discussion with this panel and audience suggests that a move to HTA 3.0 is needed. Congruent with the availability of more high quality data than ever before and the timely, agile and iterative scientific and policy processes needed in the pandemic, HTA 3.0 requires a change in mindsets and behaviours. This next evolution to HTA 3.0 may be described as "Adaptive HTA / Living HTA". This needs to be patient-centred, including effective patient involvement in all stages of evaluation and its scope should cover a wide range of new and existing treatments and health services to support discontinuation of low-value practices and make room for innovation, thus supporting efficiency and health service sustainability.

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