Scientific Panel for Health Workshop

on

‘Impact of Health Research for Society’

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REPORT
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Executive summary

Research funders and program designers are constantly challenged to maintain an effective and efficient funding system in order to allocate resources, while justifying the investments in scientific research towards their stakeholders. Estimating the returns arising from health research demonstrates accountability for public and charitable research funding to taxpayers and donors.

In the field of health research, it is difficult to describe systematically the nature and extent of the returns to the investment of a whole body of health research, some of which may inevitably be less fruitful. By definition, research activities are risky, and their returns can be unpredictable. Nevertheless, it is important to understand how underlying research is translated into benefit for patients and people, the economy and society as a whole, and look beyond financial value.

The workshop aimed to gain better insight in the nature of societal impact, as expected by different stakeholders, how to measure impact and whether impact can be enhanced through better design of research funding programs.

Impact has specific meaning and value for research funders, health care payers, patients, people and society.

In the UK, the research evaluation framework and related studies offer insight in different types of impact from biomedical and health research and ways of assessing impact. In the direct impact, a monetary gain can be calculated, as well as health gain, but there can be a long time lag. Additional impact comes from spillovers in other sectors. Besides effectiveness, it is also important to consider efficiency of the funds invested.

As a major funder, the European Commission is bound to evaluate impact of its research programs. While this process is set out in the H2020 regulation, the Commission also is building new tools for better insight, taking into account the time lag in biomedical and health research and using mixed methods. The mid-term evaluation emphasized the need to enhance societal value of the research funding programs.

The rising costs of health care are a major challenge to the social system and are not necessarily translating in improved life expectancy and quality of life. A re-design of health care, patient-centred and with clear standards to measure outcomes may curb what could otherwise become an unsustainable system. Incorporating new knowledge requires methods to assess effectiveness and above all the political will to implement changes, involving all stakeholders in the process. The patient should be a co-producer, systems should be driven by knowledge, focused on value, and meet challenges with transformation.
When considering public health, health inequalities across different social groups are not sufficiently taken into account. Prevention and health promotion remain subsidiary to ‘cure and care’ but could have major impact on public health. Multidisciplinary approaches including education and behavioural sciences can enhance effectiveness of programs. Pro-active dissemination of this evidence to policymakers will incentivize further investment for stronger societal impact.

Health gain is a major element of socio-economic impact and needs better tools. Registries and real-world data need cross-border agreed-upon standards for outcome measurements. Investigator-driven health research and implementation studies can enhance insight into effectiveness and need more support. Lastly, the workforce for implementation and assessment needs to be nurtured. Physician burnout is a threat and there is a shortage of data science experts to extract real value from the vast amount of data that becomes available.

**Assessing impact of biomedical research – an evolving field requiring broad inclusion of stakeholders and adapted methods**

Evaluation of the impact of research programs uses key performance indicators but needs to move beyond the classic numerical output data, such as bibliometrics, that policymakers have come to rely on. When assessing broader societal impact, different indicators that are project-specific are necessary. The long timeline for translation and implementation of knowledge into products should be considered. As used in the UK exercise, narratives can be very powerful to capture impact across the long timeline and an effective means of communication to the broader public.

Canada has a strong track record in impact assessment and Alberta Innovates has developed a fine-grained model to assess impact of programs on ‘health and wealth’. Important elements include the planning for impact within the program design, considering who will benefit and the long term, sustainability, with evaluations along every step of the program and beyond. This requires the use of multiple types of data, mixed methods and cross-sectoral approaches.

Patients’ experiences underscore the value of broad stakeholders’ involvement. Insights from registries depend on data quality and stimulated by an initiative of the European Medicines Agency patients were instrumental in the stakeholders’ collaboration to improve data collection and quality.

When emphasizing the importance of impact, it is equally important to consider that success cannot be guaranteed and that open, investigator-driven bottom-up discovery science can be (the start of a chain of) impactful research. This needs to be treasured, and a level of trust, and sufficient risk-taking are essential to advance knowledge and subsequent impact. ‘Negative’ data are important and need proper channels for information sharing as they are not highly valued in the classic publication channels.

Assessment of impact requires expertise and experience, and further research to optimize methodology is essential. Equally important is the inclusion of researchers to effect a change in culture and the researchers’ engagement to consider and to show the value of their research.
Designing health research for impact requires co-creation and communication

The Innovative Medicines Initiatives’ program of the European Commission was set up to accelerate the innovation process in drug development, creating a public-private partnership to share risk and data between companies and the public sector. IMI programs have been focused on outcomes that are transformative for industry and with clear value for society. Evaluation of impact is an ongoing exercise and includes developing clear communication to all stakeholders.

Public funding of health research administered through the Dutch Organization for Health Research and Development (ZonMw) focuses on promoting implementation of knowledge into action. In its activities, ZonMw includes patients and stakeholders and applies methods for impact assessment at different levels for accountability, analysis and allocation of its programs. This approach ensures data that are apt for advocacy towards policymakers.

In the UK, the government has been responsive to impact evaluations and designed new policies that include the creation of an overarching body bringing together different research councils and bodies. Impact has become part of the program design and impact must be embedded in research proposals and reporting. The methods for assessment need however further refining to be ‘minimally invasive’ and as noted above, this requires dedicated expert research, as part of developing science on science policy.

The health programs within the European Commission are geared towards moving beyond evaluation of reaching program objectives and increasing impact. This requires translation of outcomes data in actionable plans for health care. Focusing on implementation of knowledge, the Commission can take a lead as a broker across borders, and work with member states. Sustainability is one of aims.

As a charitable foundation Wellcome, is engaging with the research community and with the public in program design and in evaluation of impact for society. Wellcome uses different indicators to measure success and considers policy changes as one of the higher levels of impact. A continuous and in depth public dialogue, including addressing controversial issues, is part of the process.

At INSERM, general principles guiding research policies for funding seek to balance programs with short- and long-term impact, and between society’s priorities and objective needs. Creating political will to address barriers for implementation of research results needs the gathering of all stakeholders, including patients and payers. Anticipating and addressing ethical issues that may arise during implementation reduces later barriers.

Co-creation and broad stakeholders’ engagement during project planning (funding stage), translation and through the innovation chain are means to enhance impact. The final steps of pricing, reimbursement and access to products must be part of the planning and payers should be involved at early stages. Comprehensive, long-term follow-up and cross-border collaboration will enhance impact.
Conclusions and recommendations

- Societal impact of health research includes but is not limited to economic return. Economic return can be calculated and is substantial. A long time-frame must be taken into account.
- Health gains, reducing inequalities and cost containment of health care are specific aims for impact of health research. Health research needs better tools for achieving these specific impacts, including cross-border standards and high-quality data on outcomes.
- Implementation of research results to achieve these impacts requires transformative action with a culture change in the professional and research community, and inclusion of dedicated data scientists.
- Research projects should be designed in co-creation with all stakeholders, putting health promotion and patients’ outcomes at the centre, planning for impact from the start and anticipating on potential barriers to implementation.
- Indicators for success need to be defined and followed through the course of projects and beyond. Sustainability is essential for health impact.
- Communication and public dialogue are essential to achieve societal impact and engage with policymakers.
- Evaluating and facilitating impact requires expertise. Increased investment and research on impact evaluation are necessary.
**Introduction**

The value of scientific research investments needs to be demonstrated to enable effective and efficient allocation of limited public and charitable funds, and to ensure accountability to donors and taxpayers. This is complex for medical research as activities are risky with often unpredictable returns, and value is not solely economic: a broader societal perspective is required to truly understand research impact for patients. To do this, hearing the voices of different stakeholders is essential. Communication and participation in the assessment of impact at all stages of research are important and emphasized throughout this workshop.

**Philippe Cupers** from the European Commission (EC), DG RTD, Directorate Health, officially opened the workshop, stressing the need to deliver impact for the EC research programs under Societal Challenges, and emphasizing that to do this we need to improve our understanding of how we can have and measure impact.

**Karin Sipido**, Chair of the Scientific Panel for Health (SPH), welcomed participants to the workshop, outlining its objectives. The workshop aims to explore and highlight the societal value of health research with aim to facilitate better assessment of, and increase impact. She described the SPH’s tasks and role as an inclusive and complementary platform to consult with and bring together the views of a wide range of stakeholders in health research to develop a vision on a strategy that will deliver impact. During the latest conference in June 2017, the SPH presented the need for a long-term mechanism to ensure a more comprehensive and impactful health research policy in Europe, in the form of a European Council for Health Research. This will help ensure that the future of health research in Europe is cohesive, people centred, mission oriented, and ensure synergy across geographic and disciplinary borders. The workshop will contribute to developing this concept and the SPH proposal.

**Jonathan Grant**, Director of the Policy Institute, Professor of Public Policy and Assistant Principal for Strategy, King’s College London, United Kingdom, stressed that the social contract between experts and citizens is now being challenged, and that there is a strong need to measure and communicate impact. He gave a definition of impact as ‘an effect on, change or benefit to the economy, society, culture, public policy or services, health, the environment or quality of life, *beyond academia*’ and emphasized through the discussion of multiple case studies, that both qualitative and quantitative methods of assessment can be utilized to measure impact. The qualitative case studies discussed illustrated that

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impact and the pathways towards it are diverse and unpredictable, and that knowledge does not carry a passport - research can have a global impact. Quantitative assessment of impact was illustrated by a case study which assessed the economic returns of research. It captured economic return in terms of net health gain (disease-specific) and the ‘spillover’ or GDP gain (disease-independent), enabling expression of the rate of return in a concise way that will engage finance ministries. Four elements of information went into assessing the rate of return on investment: research investment, monetary benefit, the research-attributable proportion of the health gain, and the time lag between research investment and health gain. The complexity of making quantitative estimates was discussed through the concept of elasticity in spillovers (i.e. money invested in the private sector may lead to gains in the public sector, and public sector investment can attract private investment). A word of caution was given on research waste and the need for efficiency: Waste has been estimated at 85% in one study.

Professor Grant concluded by emphasizing the importance of conducting research on research, and by saying that the use of mixed methods is desirable for the measurement of impact.

Session 1. How do scientists, policy makers and citizens look at health and biomedical research impact?

**Susanna Palkonen,** European Federation of Allergy and Airway Diseases Patients Associations – European Patients Federation and SPH member, introduced the session and emphasized that for patients, impact of research is crucial.

**Giorgio Clarotti,** Senior Policy Officer, Health research strategy, Directorate-General for Research and Innovation, European Commission, began by noting that framework programming accounts for 10% of available public funding in Europe. To date, ten joint program initiatives (JPIs) have been launched by the Council of the European Union, on diverse topics. Societal impact has now been added as a priority for the assessment of joint programming initiatives. A methodology for the assessment and attribution

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of impact was developed, but estimation remains problematic due to complex factors including time lags and finding proxies that facilitate prediction. Consequently, the use of mixed methods is important. A couple of approaches to measuring impact were given: monitoring through involvement of a panel of stakeholders\(^5\) from research initiation; and considering requests to join initiatives from international funding agencies.

Horizon2020 (H2020) is the biggest publicly funded single research program in the world and is highly successful, but as an instrument of the European Union, it is also constrained by the Regulation that sets out its mandate and rules for implementation. The interim evaluation of H2020 was conducted through looking at five evaluation criteria. The High-Level Group, chaired by Pascal Lamy, formulated 11 recommendations\(^6\), two of which referred to impact: Designing the EU Research & Innovation program for greater impact, and, capturing and better communicating impact. The experience with H2020 highlighted the importance of managing expectations in relation to the time lag between research and impact and the challenge of attribution when conducting multidisciplinary, multi-country research.

**Stefan Larsson** of the Boston Consulting Group and founding member of ICHOM, opened by emphasizing that health systems’ sustainability is under pressure: Healthcare costs are growing at twice the rate of GDP due to aging populations and so healthcare spending has diminishing returns. We invest more and don’t gain adjusted life years from our spending as we have a fundamental productivity challenge. Scientific and technological progress has led to an exponential growth of medical knowledge, but we need to apply the knowledge better – we need to work out how we can apply it and integrate research into normal clinical practice. Taxpayers are happy to pay more for better health, but this productivity challenge has led to a great deal of frustration. Within the system, work conditions are less and less acceptable, as exemplified by physicians’ burnout. At the World Economic Forum, it was concluded that the future health care system needs to be patient centred, and that our definition of success has to be improvement in health outcomes\(^7\) relative to resources spent.

We need to conduct analyses on population segments, including prevention and treatment with segment-specific interventions. Precision medicine requires connected data sources, and the technology is available to achieve standardization of security and data management. We need to implement health system digitalization to facilitate large datasets, and international standards to enable data pooling and learning across borders. ICHOM set out to develop global standards\(^8\) for outcomes measurement,

\(^5\) A panel of stakeholders could be presented with questions such as: 1) do you think the strategic research agenda is right, have the appropriate topics been selected for the call, have the appropriate projects been selected?


\(^7\) Health outcomes which are selected as they are meaningful to patients

\(^8\) So far, 23 diseases have been completed which represents over 50% of disease burden. 17 sets have been published in peer-reviewed journals.
disease by disease, in close cooperation with patients and clinical leaders. Higher resolution data and international standardization\textsuperscript{9} could bring many benefits through facilitating better comparisons\textsuperscript{10}. A coherent health system strategy and reform agenda for population health is necessary. We need benchmarks, and decision support tools, plus a delivery organization - systems. We need to look at incentives and payment models. We need supportive policy that focuses on outcomes that matter to patients, and we need transparency. Finally, we need strong political leadership with long-term perspective, as well as a constructive and fact-based debate, and broad stakeholder engagement. Unless healthcare undergoes major disruption through an economic crisis, a gradually more and more difficult situation will develop. To overcome this, it is essential that policy makers are willing to look at numbers and agree that there is a need for significant change.

\textbf{Panelists}

\textbf{Susanna Palkonen} emphasized that the impact of health research is everywhere in our daily life. However, the impact often doesn’t reach the citizen in an understandable way – it remains unclear as to which information is evidence-based. People can mix emotions, data and experience. What needs to come out of health research is a more consistent, strongly communicated message. That information needs to have a broader reach, not just confined to groups with privileged access.

\textbf{Caroline Costongs}, Director of EuroHealthNet, discussed the need to reduce health inequalities rooted in economic circumstances, living and working environments, and broader social and economic determinants. She asked, ‘How can we increase our capacity to improve the health of people?’ ‘How does health link to upstream determinants and the challenges in society?’ ‘How does it fit into the Sustainable Development Goals (SDGs)?’ She emphasized the need for sustained investment with a broad agenda, and a focus on the implementation of research and the effectiveness of interventions: There is a need to take a socio-economic perspective in research and therefore to work beyond traditional collaborations and include political, economic, education, and behavioural scientists. We

\textsuperscript{9} e.g. For capture: development of a standardized measures library, defining data types including data sets of outcomes and metadata for value-based health care; For mapping – establishment of a common language and template to map the measures library to existing ontologies and data sources; For access – establishment of a data access infrastructure. Such databases would enable better hypotheses for the segmentation of population and global clinical “randomized registry trials” for better outcomes.

\textsuperscript{10} Standard metrics could gather outcomes results from a large number of patients worldwide which would enable better comparisons of populations and more precise treatments. Higher resolution data could enable analysis of providers, ad generate hypotheses for system improvement for example.
need to look at impact across the social gradient\textsuperscript{11}. We need to invest in more advocacy and pro-active dissemination of evidence to policy-makers. No progress has been made in the reorientation of health systems towards prevention and health promotion, rather than cure and care. If we look more carefully at how we invest, then closer cooperation in data monitoring and health research would increase impact for all.

**Panel discussion.**

All of the speakers were invited for Panel discussion. They were and joined by Anna Pank, Director of International Development, Global Impact and Outcomes at JDRF, and Bernard Charpentier, Chair of the Federation of European Academies of Medicine (FEAM), and member of Science Advice for Policy by European Academies (SAPEA).

Participants reiterated that impact is a topic of growing interest and holds great importance for funding organizations to demonstrate the value of the work that is done. A number of ways to increase impact were discussed:

**Registries are important and need more support.** Research should focus on societal benefit. Presently there is inequality in care and insufficient evidence to support selection of the best drugs. Registries, such as the Swedish diabetic registry, provide scientific knowledge and real-world data that can impact patient management and care, and have a political impact as well.

**More funding is needed for conducting clinical research on humans in the clinical context** as the level of funding is too low at both the national and European levels. It is more difficult to find funds for conducting clinical research than for basic research (animal model), yet investigator-initiated studies are generally multi-centre, with large study populations which makes them expensive to perform. A greater focus on translation from basic science to clinical practice will improve the impact of research.

**Political decisions need to be made that reduce the distance between research and clinical practice.**

**The EU needs to better structure the funding of translational research.** It is better structured in other contexts (e.g. NIH) and translation will improve through better measurement of patient outcomes.

\textsuperscript{11} Impact can differ in different populations. In addition, often people who are deprived and in lower socioeconomic circumstances (for example migrants, prisoners, and other vulnerable populations) are less visible or underrepresented in health research.
Standards for core outcomes need to be agreed upon to facilitate cross-border analyses of health data. ICHOM is an example of a successful methodological approach for developing a minimally sufficient set of outcomes based on validated metrics and registries.

The exponential growth in data and new technology needs to be met with sufficient expertise in data science to enable translation of data from information to knowledge. There is a shortage of experts in the field and we face a bottleneck.

The way we involve, and communicate science to, patients and citizens needs to be improved. 1) To ensure societal needs are met, patients and citizens need to be included from the research planning stage. 2) We need to improve understanding of the time-lag in research – that what we invest now will benefit the future generation. 3) More budget should be spent on health promotion. 4) Discourse should centre on health research rather than disease research.

Session 2. How to evaluate the impact of health research?

SPH members Martin Buxton and Stephen Holgate gave a short overview of Session 1, noting that we heard about the diversity and complexity of health research impact, and how it interacts with systems. They then stressed that we now need to make steps towards measuring it. The discussion of how to evaluate health research impact is the objective of this session.

Koen Debackere, Professor at the Faculty of Economics and Business, KU Leuven, and member of the Network for Advancing and Evaluating the Societal Impact of Science (AESIS), noted that defining impact is difficult, and there is a need to take a multifactorial perspective. He provided four concrete areas for improvement: 1) Profiles are important in value creation: While policy makers want to see impact reduced to one number, this does not work. Citation rates as an indicator of impact should be considered but not in isolation. 2) There is a need to move beyond scientific impact, and there is a need for project/program-specific Key Performance Indicators (KPIs). 3) Fine-grained KPIs are needed. This would help us to go beyond counting citations, spin-offs, or other simplified indicators. Stakeholders’ needs are to be matched with available data sources to define relevant KPIs. 4) There is a need for impact sophistication – we need to complement data with narratives as sometimes this is the only way of capturing it. The interdisciplinary nature of development, and the time needed to translate research to clinical practice was highlighted using examples of a cochlear implant and a 3D printed jaw bone. While data is a vehicle for communication, impact is not a simple, linear process and thus more difficult to capture using data and process narratives.
In innovation literature, we always talk about time compression, and this can occur after concept development, but to move from 0 to the end point takes time. If we are not patient, we will not deliver a solution to patients. To conclude, impact is a function of doing excellent work, as well as professionalism, resources, and time: Impact = f(excellence, professionalism, resources, time).

Kathryn Graham, Executive Director of Alberta Innovates, Canada, noted that the demand for greater investment comes with a demand for greater impact and that planning for impact increases the likelihood of achieving impact. In Canada, Prime Minister Justin Trudeau has put in place the need to monitor impact and report back to Canadian citizens, and a new Government of Alberta mandate states that research and innovation should be outcome focused. Dr. Graham posed the question “how do we best capture the impact of our investments in health?” In response to that question, she recommended a preferred framework: The Canadian Academy of Health Sciences (CAHS, 2009), Health Impact Framework which is based on the Payback Model the most widely used and implemented health impact framework model in the world. In the province of Alberta, which has a long history of assessing impact, and where four cross sector research funding agencies were consolidated into one funding organization - Alberta Innovates. The CAHS framework was implemented in the health sector as it was contextualised to Canada and provides pathways to the broader impacts in terms of health and wealth of Canadians. It also provides a set of tools: 5 main impact categories: advancing knowledge, capacity building, informing decision making, broader health and socio-economic benefits as well as a menu of 66 indicators that are mapped across the pathways of how research can move to contributing to broader impact.

When it comes to assessing impact, there is no magic bullet – it is hard work. Assessment should not just look at what the impact is, but in higher resolution, include who is impacted. Alberta Innovates uses the CAHS framework for planning, assessing, measuring and communicating impact. Implementation of the framework includes following a ‘fit for purpose’ a protocol that was developed for the International School on Research Impact Assessment (https://www.theinternationalschoolonria.com). This grass roots community-based protocol comprises of 6 blocks: 1) Understand the context; 2) Identify the assessment purpose; 3) Define indicators of success; 4) Develop the design, methods and data collection; 5) Communicate (results are used); and 6) Manage the assessment (on time, on budget, quality, deliverables). The CAHS framework was implemented across the organization and diverse programs using the 6 block protocol. This allowed the evaluation of impact to be systematic and enabled better governance and management– with the ability to look horizontally across programs rather than just at individual programs. Performance management and evaluation is embedded within the program life cycle, and impact planning occurs up front prior to program implementation, as well as during the program to make course corrections and retrospectively at the end. Impact is also considered in terms of sustainability. The CAHS framework was also used by the National Alliance of Provincial Health Research Organizations who worked collectively to harmonize the measurement impact for benchmark purposes at the provincial, national and international levels. Another example is the Canadian Health
Services Research Alliance who focus on decision making impact of CAHS and includes diverse perspectives as well as the voice of the patient. Implementation of the framework using the 6 block protocol allows for customization and regional differences, as exist in Europe. Key lessons have been to use multiple types of data, mixed methods, cross-sectoral approaches, and plan for impact up front.

Christoph Thalheim, Director of External Affairs at the European Multiple Sclerosis Platform, shared the example of how the Multiple Sclerosis (MS) Data Alliance leads to impact. This alliance covers more than 700,000 people with MS in Europe, with 39 member organizations in 35 countries. The alliance aims to set standards, to harmonize patient-reported outcomes (measures), and to develop and implement tools for data discovery and harmonization. More and more, health research bodies and payers look at real world evidence. To evaluate impact, you need comparable, meaningful, and reliable data. Data should be collected and used according to the FAIR guiding principle: Findable, Accessible, Interoperable, Reusable, to have maximal impact. In 2015, the European Medicines Agency (EMA) created the patient registries initiative. More recently, they clearly defined what they wanted to achieve with a more systematic standardised approach to risk-benefit evaluation of medicines. The MS data alliance identified 26 registries in Europe. They aim, through stakeholder collaboration, to unify data collection, ensuring that it is of high quality and easily transferable for every condition. Stakeholders work together to determine which standards to apply, and this leads to certification by the EMA. Lessons learned from the patient registries initiative have been that: joining forces with the EMA was the way to get the necessary attention, that fundamental changes take time, and that the EC has be a fantastic partner for patients. He noted with great disappointment the lack of continuity or sustainability (the European patients forum has been included and then excluded from sustainable funding).

Panelists

Walter Ricciardi, President of the Italian National Institute of Health, noted that health demands coincide with changes in global demography. To generate impact, we need a new solution to respond to challenges. Until now, health systems have been doctor-centred, but expectations are changing, and 21st century healthcare should be patient-centred. We need to support evidence informed decision making and answer fundamental questions. The patient should be a co-producer, and systems should be driven by knowledge, focused on value, and meet challenges with transformation. The TO-REACH (https://to-reach.eu/) consortium was described. It was established to identify common challenges and organizational needs in European healthcare; propose possible solutions to improve health system performance; and to identify the most effective ways to organize, manage, finance and deliver high quality, sustainable and equitable care to European and global citizens.

Mairead O’Driscoll, Interim Chief Executive and Director of Research Strategy and Funding, of the Health Research Board Ireland, stressed that the mornings sessions emphasized that we need to go
beyond academia. She noted that in many ways, measuring economic impact is the easier aspect and that measuring societal impact is much harder as we don’t have the methodologies available to do it. She stressed that we need to coordinate our methodologies, collaborate, and take a collective approach. This is not just about what we fund, but about how we fund. We need to think about bringing the users of research – the patient and public perspective - into the process much earlier. This will require a culture change for funders and researchers.

**Panel discussion.**

*To track KPIs forward for long time horizons (e.g. 20 years), KPIs need to be revisited.* KPIs are not carved in stone and new avenues may emerge. A system needs to be in place to monitor them. In Alberta that includes three levels of activity: discovery, application and use (e.g business creation).

*Many big innovations were not foreseen when the grants were written. Does impact measurement enable us to identify prognostic markers to determine whether a program will work or not? What characteristics, e.g. creativity, should we look for in a project to know if it will be successful?* This question, regarding predictive and leading indicators, is one that those working in the field are always trying to answer. If we are able to find leading indicators, then impact will be more likely. We need to conduct natural experiments and use quasi-experimental design to learn and then share what works and what doesn’t work under different conditions. Currently the funding system is more “faith-based” (or trust-based) than evidence-based.

*Wellcome is using the researcher’s track record as key indicator of funding. Does it work?* Wellcome doesn’t have to answer to tax payers, but as independent foundation it has an internal accountability. They are in the process of implementing a new success framework for this. Claiming impact in some fields (e.g. policy) is more difficult than in others, but often you know yourself whether you can claim that things you have done have led to policy change. That’s where the researchers track record comes in. Funders have to be comfortable with a certain degree of subjectivity when evaluating impact.

*Strategy should be balanced between success and risk.* When putting money in projects with expected success, there is a danger of avoiding risk. But risk is where discovery comes from, and often progress comes incrementally, e.g. hip replacement, step by step improvements. As an example that may reflect avoiding risk, the NIH is funding more people over 65 than under 35.

*Context is important when defining success.* The Canadian example illustrates the importance of context. Some aspects of health systems are generalizable, others are culturally driven. The challenge is to find the simple aspects that are transferrable. Within Europe, we need to consider how success is
defined in different European countries, not only countries in the geographical West of Europe. The To-Reach project aims to tease this out.

**Funding mechanisms that allow continuity are needed to ensure sustainability.** Short funding cycles (e.g. 3-4 years) waste resources because successful collaborations that have been established have to stop. Funding horizons should be sufficiently long and match that of the program cycle to enable long term measurement of impact. EIT-Health was given as an example as currently funding horizons are 7-years long, but good projects could be operational for 15 years. Sustainability can be improved by having multiple funding sources.

**Impact could be misunderstood as producing positive results.** Negative results are essential for progress to be made in research. Negative results need to be published, and shared. From the perspective of funders, a bigger problem than funding a failure is supporting the generation of knowledge that is subsequently lost. The idea of offering funding opportunities for systematic research on research was raised.

**Session 3. How can health research be designed in ways to maximise achieving impact?**

SPH members Ildiko Horvath and Dainius Pavalkis introduced the speakers and emphasized that disruptive change is needed for research to have more impact in clinical practice.

Pierre Meulien, Executive Director of the Innovative Medicines Initiative (IMI), shared lessons learned in the 10 years since the initiation of the Innovative Medicines Initiative (IMI). The healthcare environment is complex and driven by numerous drivers including science and technology, the epidemiology of disease, the role and behaviour of the consumer, and economics. IMI was set up to accelerate the innovation process in drug development because the process is complex, lengthy, risky, expensive, and inefficient. Working on topics that lend themselves to pre-competitive research, public-private partnerships (PPP) provide the opportunity to share risk and data between companies and the public sector, to include stakeholders from the beginning, and to provide value to the private sector, the EU and public at large.

To optimize the probability of good outcomes, it is important to look at the framework within which IMI is working to understand the value proposition to the European Parliament, how to communicate the value, and how to design challenging programs. The IMI evaluation framework is still evolving to provide clear, achievable, and practical objectives, with intermediate outcomes along the trajectory for long-term impact. IMI’s objectives are to understand disease and its complexity and accelerate research into translation.
IMI created a logic model of PPP that developed into an ecosystem. Selected research topics address societal challenges but focus on challenges for industry that require input from the public sector, universities and SMEs. Outcomes should be transformative for industry and have clear value for society. Projects are performed in an international cross-sectoral community to address medical needs.

Several aspects can still be further streamlined: the link on global scale for global issues (e.g. dementia, antimicrobial resistance); measuring performance and impact on society; including other industrial sectors necessary for health innovation; making it easier for stakeholders to join IMI projects; and communicating the value of IMI to spread the success and counter misconceptions.

Wendy Reijmerink, senior staff member Strategy & Innovation at the Dutch Organization for Health Research and Development (ZonMw), discussed how to improve impact and societal value of health research from a funders’ perspective. Value in research can be ensured by achieving impact, assessing impact, and advancing impact (Triple A). When accountability, analysis (good governance) and allocation (institutions, people, fields of interest) are tackled correctly, advocacy (4th A, making the case for health research) follows automatically. ZonMw stimulates and funds health research, healthcare innovation, and the application of new knowledge to improve health and (health) care.

ZonMw is an independent broker between policy, practice (healthcare insurance, professional institutions etc.) and research. It positions itself as a knowledge partner that participates in quality/innovation cycles, facilitated by a 1998 law that assigned ZonMw the task of promoting implementation of knowledge into action responsibility.

To reduce waste in research, a framework was established with criteria and indicators for design and evaluation of responsible research practices, covering 4 major themes: societal relevance, scientific quality, integrity, and efficiency.

ZonMw defines (societal) impact in terms of the use of knowledge in policy and practice. An important driver are productive interactions: collaboration with relevant stakeholders, co-financing or in kind contribution, user-oriented products or tools, targeted dissemination and implementation activities.

It was additionally noted that further research on research is necessary to ensure the value of the underlying evidence for impact, and that we need to rethink research culture and change behaviour: how can we motivate people to show value in their own research?

Ian Viney, Director of Strategic Evaluation and Impact of the UK Medical Research Council (MRC), shared how the impact agenda had developed in the UK. As far back as 2006 the research councils worked together to maximise research impact and improve the way that benefits of research could be evidenced and communicated12. When research councils introduced a “pathways to impact” section in their grant applications this was initially met with objections from the research community. Researchers were understandably concerned that there would be a shift from basic to more applied studies.

12 https://www.ukri.org/innovation/excellence-with-impact/
However, the MRC has maintained the support for discovery science, while using additional strategic funding to build capacity and support new opportunities in translational medicine, including working closely with industry.\(^{13}\) Combined with the introduction of impact assessment in the Research Excellence Framework (REF) in 2014, thinking about the potential for impact from research has become business as usual.

The research councils also introduced a new process to prospectively and systematically capture feedback from researchers about output.\(^{14}\) This has provided a comprehensive view of progress, productivity and quality of their portfolios. The collection of this information also met with objections from the research community, concerned about an increase in reporting burden. However, the structured online process has replaced final grant reporting for the research councils, and is now used by over 80 research funders in the UK and internationally.\(^{15}\)

Several useful econometric studies have highlighted the positive return on public investment in medical research\(^{16}\) and these in combination with being able to evidence research benefits to the economy and society, have led to strong bids for continued Government support for research in successive Government spending reviews. The UK Government has recently announced its aspiration that UK spending on research and developed be increased to 2.4% of GDP to help drive economic growth. In April 2018 UK Research and Innovation will come into existence bringing together all 7 research councils, as well as Innovate UK and Research England. This new agency will command a budget of more than £6 billion a year and the mission to push the frontiers of knowledge, deliver economic impact and create wider social and cultural benefit.\(^{17}\)

The MRC continues to develop its approach to evaluation within UKRI. The availability of systematic information on research output is an important part of the way that we plan for impact and design monitoring and evaluation for our research programmes. The launch of the UK Prevention Research Partnership (UKPRP)\(^{18}\) is a recent example of a programme where evaluation is guided by a theory of change, and regular reporting of outputs and expert review is used to monitor progress. The UKPRP is a


\(^{14}\) [https://www.ukri.org/funding/information-for-award-holders/research-outcomes1/](https://www.ukri.org/funding/information-for-award-holders/research-outcomes1/)

\(^{15}\) [https://www.researchfish.net/](https://www.researchfish.net/)


\(^{18}\) [https://mrc.ukri.org/research/initiatives/population-health-sciences/ukprp-initiative-launch/](https://mrc.ukri.org/research/initiatives/population-health-sciences/ukprp-initiative-launch/)
partnership between 12 UK funders that have agreed to commit at least £50 million additional funding to support prevention research, with the aim of introducing new interventions into practice to reduce non-communicable diseases.

Stefan Schreck, Head of the Unit Health Programme and Chronic Diseases, Directorate-General for Health and Food Safety, European Commission, stressed that a culture change is needed to plan for impact and to facilitate having impact in the planning process.

In the past, projects were considered successful if scientific objectives were reached, however a project is only successful if it is applied and implemented in society. For example, the International Rare Diseases Research Consortium (IRDiRC) reached its scientific objectives in 2016 yet despite all EU tax payers contributing, only half of the EU population has access to the new medicines and there is no single country in the EU where all drugs are available. This situation is not sustainable.

We need to move beyond thinking just about research, towards thinking about implementation. If there is a new approach that requires multi-sectoral collaboration, then we need to find common objectives, distribute tasks, and provide financial support for programs. The EC can facilitate knowledge transfer as in the example of cancer screening. In the Netherlands, colorectal cancer screening started in 2003 but it took 11 years of preparations to get to implementation at the population level. The EC is now facilitating knowledge transfer from countries where screening has been implemented to other member states to make screening available for all EU citizens.

A similar approach as taken by ZonMw at the European level may help to ensure knowledge transfer.

To measure success, we need a higher level of granularity. For each mission we need to identify specific indicators. Institutional follow up is essential to ensure sustainability as research results lose value without regular update. However, this is difficult in the current framework programs. For some projects there are ad-hoc solutions to attain sustainability but this is not enough.

Panelists

Stuart Pritchard, Manager European Union and Public Affairs, at the Wellcome Trust, asked “what do we, as funders and community, mean by success?”. He emphasized that this was not an impact agenda that would be imposed on others, but a means of evaluating what is done at Wellcome. This comes back to responsibilities – the responsibility to talk about the research that Wellcome funds, and the responsibility to enable success. Wellcome wants to maximize impact, beyond academic impact, to societal impact. Biomedical projects, basic and translational research, are funded, as well as projects in the humanities. The social contract is a strong consideration, and to ensure impact, researchers should bring the necessary partners on board from the beginning. Impact and continuity principles are important and need careful consideration – “Are these implemented in the review process?”, and “If/where/when patients should be involved?” – yet, leaving also academic freedom to the researchers.
As an independent foundation, Wellcome has the flexibility to take risks. The organization is developing and implementing a success framework using a basket of different indicators. It will be an outcome-based approach and will use a common language across projects. Wellcome is also evaluating its role in engaging with policymakers and the public, considering how the policy team can have maximal impact and whether there is sufficient support for the public dialogue. Scientists need to be able to engage in public dialogue around controversial issues. This communication is important and Wellcome invests in activities reaching out to the general public and enabling conversations on ethics that will arise on implementation. Changes in policy are evidence of impact, e.g. in the implementation of mitochondrial donation.

Valerie Mazeau Woynar, Director of the Department for Partnerships and External Relationships, INSERM, shared that at INSERM, 15,000 people perform research towards better health, policy guidance, patient and public information. Research is guided by three principles:

1. Balance in the process of priority setting. This implies that INSERM seeks to balance priorities for research programs between short- and long-term impact, and considers balance between EU and national efforts. INSERM also seeks to balance between what society wants and what society needs (but doesn’t see yet).

2. Political will to create programs that involve all stakeholders. Programs need to anticipate barriers to implementation and innovation, do the necessary research on these barriers and address them. This can involve developing methods to evaluate innovation, training for new jobs, organizational challenges. Involving all stakeholders means including patients, health care professionals, researchers from different disciplines, payers, regulation agencies, industrials, governments.

3. Anticipating and incorporating ethical aspects of future translation of results into the programs to facilitate eventual implementation. Considering exponential growth of knowledge and technologies, it is likely that future research implementation will raise ethical questions, e.g. genomic medicine.

Panel discussion

European researchers are excellent at knowledge generation. The insufficient translation is an ecosystem issue and not to be viewed as a funders’ issue. To make discovery knowledge available to those who can take it further for translation, interfaces need to be improved. These interfaces are PPP and could be enabled through integration into projects.

Through joint incentives/principles we can try to harmonize individual efforts in different countries. We live in a network society but the EU has a specific responsibility to coordinate and synergize the efforts. There are initiatives in this direction but currently insufficient.
Researchers should involve the relevant stakeholders from the outset. Different communities in different disciplines can be doing research in relevant domains for a single issue, e.g. air-quality. For this research to translate, it needs to be brought together, and this must be anticipated when setting out a research agenda.

Impact is very difficult to evaluate at the funding stage but a comprehensive follow-up can identify long-term impact. All proposals submitted to Horizon2020 are evaluated against three criteria: excellence, the implementation plan, and impact. A better framework for impact is needed and should capture the long process of impact across different projects. Currently such memory is lacking. Engaging researchers in this more global approach and pooling of the work could identify impact across different projects.

Improving access to and affordability of products is essential. Mechanisms such as introducing access plans in agreements, or instruments such as equitable licensing can speed up availability to a larger patient population and thereby increase impact. Such approaches should be considered early in the process of translation.

Research and pricing systems should be better connected. There are multiple steps between research results and an eventual product, where different systems (for funding, regulatory, and reimbursement) and actors are involved with different interests. It is difficult to put a value on the first set of research data that lead to the product authorization stage. There is a need to induce a pull mechanism from all those who pay (as the push mechanism for technology is already good), so that those who pay better determine which products or technologies patients get access to.

Breakout session

In the final session of the workshop, a set of questions were discussed at five roundtables, each chaired by an SPH member.

Reflections on the measures for societal impact as discussed during the day: Are they adequate? Are additional measures needed? How should impact be reported back to public, policy makers and funders?

- It is important to clarify that science ranges from discovery through to application, and that economic impact is part of societal impact - they cannot be separated.
- The implications of research for the public must be considered up front, with as examples sensitive areas such as genome and stem cell research. The public, policy makers and funders need the same
information, but in different formats. Including and educating the public to improve health literacy, through sharing results and explaining the content and implications, is essential.

- If patients are involved in a project, they could participate in reporting, adding a pitch for a broader audience.
- Although additional impact measurement methods would be beneficial, foremost we should make the effort to use existing tools more widely.
- Impact outcomes and measurement should be considered from project initiation, acknowledging that over time they will need to be revisited to ensure they remain relevant.
- Frameworks should remain flexible, adapted to different projects and allowing sufficient academic freedom.
- It is important to bring together views and ideas from all member states and aim for equity and inclusivity.

**Do we invest enough on monitoring, measuring and attempting to maximize impact?**

There was consensus that we do not invest enough. A first good step would be to perform research on research, as a recognized discipline, with appropriate funding.

**What sort of policies and funding models need to be developed for health research – designs to give the greatest opportunity of early societal impact?**

- To enhance impact, a comprehensive participation of stakeholders, including society and patients, is necessary for setting the agenda and determining how challenges should be solved.
- Better coordination of EU and member state level funding is essential, including the creation of infrastructure, and investment in people.
- Eventually policymakers set the research agenda and must maintain a proper balance between bottom-up and top-down funding mechanisms.
- There are still large inequalities within Europe with regard to research opportunities that need to be addressed. This will avoid brain drain and consequent impact on health care. Participation in outcomes and implementation research will spill over in better health care.

**What steps could be taken to involve the eventual users of research (including industry across the board) in identifying research questions and designing new ways of delivering results for more rapid conversion into public benefit?**

- Involving end-users in the program. Through consultation and participation, end-users may help to identify themes or needs. However, the eventual phrasing of research questions is the task of a scientific board. The Netherlands have experience in this approach.
• Design. Creating impact is a collaborative effort that should be implemented in the project management from the beginning. Too often this is considered only when research results have been produced and are transferred. A feedback loop from the impact back to the researchers could incentivize early implementation and planning for impact.

• Translation. There is a need to improve the technology transfer from academia into application and expand dedicated technology transfer offices to facilitate this process. Capital is required to put this into practice. Entrepreneurship in Europe is different from the US and we should look at the areas where Europe has a competitive advantage.

• We need to improve the ‘implementation’ of research results using a system-wide approach.

• Ethical aspects of research should be considered up-front during planning and allocation of funding.

How can research and its potential impact be communicated to change individual health behaviour, or how individuals think about health? Consider the impact of communication through social media – at the societal level vs individual level, for example the role of social media in vaccine hesitancy / aversion of generic medicines?

• Many levels of communication exist, including internet searches and social media, which is a primary source of health information to many citizens. The challenge of social media for the medical community is to identify for patients and citizens which information is evidence based. Social media remains self-regulated.

• We need to consider who should communicate health research: Researchers? Health care providers? Patient organizations? Currently, many researchers are not very good at communication to the general public. Researchers also have incentives to overemphasize the importance of their research, which might create public mistrust. There is strong pull from the science community to spend funding on research, but when performing research projects, we could allocate a portion of the budget (e.g. 10%) to spend on communication.

• With regard to ethics, there is a need for responsible communication of research. This could be achieved for example through communication at the institution level via a legal authority for health communication, or through the development of ethics schemes on how to communicate.

Concluding remarks

The SPH Chair, Karin Sipido and SPH Workshop Leads, Stephen Holgate and Susanna Palkonen, thanked all participants for their active engagement in the workshop.
The SPH Chair reminded participants that it is the role of the SPH to bring diverse views from a wide range of stakeholders to the table, across disciplines and fields in health research, healthcare and public health. Ensuring impact in healthcare research requires a strong involvement of patients and a patient-centred system. This has not yet been achieved.
Acknowledgements

Sincere thanks Marc Baay, Sally Jackson, Anke Stuurman, Yoem Tran, and Nora Anton, for taking notes of all presentations and discussions during the workshop and writing and editing the workshop summary report.
Scientific Panel for Health Workshop
on
‘Impact of Health Research for Society’

CDMA building, rue du Champ de Mars, 21
1050 Brussels, Belgium
Room SDR 1&2

Thursday 8 March 2018

PROGRAMME
Workshop leaders
Stephen Holgate & Susanna Palkonen – Members of the Scientific Panel for Health

Aims of the workshop:

The aim of the workshop is to explore and highlight the impact and societal value of health research, to discuss how to assess and increase impact. The workshop will build on expert and stakeholders’ experiences, examples and perspectives.

Towards this end, three questions are addressed:

- How do different stakeholders - scientists, policy makers, citizens - look at health and biomedical research impact?
- How to evaluate the impact of health research?
- How to design health research policies to maximize societal impact?

Research funders and program designers are constantly challenged to maintain an effective and efficient funding system in order to allocate resources, while justifying the investments in scientific research towards their stakeholders. Estimating the economic returns arising from health research demonstrates accountability for public and charitable research funding to taxpayers and donors. Because resources used for publicly and charitably funded medical research, could potentially be put to other purposes for the benefit of society, there is an obligation to demonstrate that such investments represent good value.

In the medical field, it is difficult to describe systematically the nature and extent of the returns to the investment of a whole body of medical research, some of which may inevitably be less fruitful. By definition, research activities are risky and their returns highly unpredictable. Nevertheless, it is important to understand how underlying research gets translated into benefit for patients, the economy and society as a whole.

In the evaluation of societal impact, it is important to hear the voice of different stakeholders, not in the least society, and to consider impact beyond financial value. The importance of communication and participation are cross-cutting themes for the workshop.
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<tr>
<td>08.30 – 9.00</td>
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<td>Why do we need to pay more attention to the impact of health and biomedical research?</td>
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<td>09.30 – 11.00</td>
<td>Session 1. How do scientists, policy makers and citizens look at health and biomedical research impact?</td>
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<td>Giorgio Clarotti – Senior Policy Officer, Health research strategy, Directorate-General for Research and Innovation, European Commission</td>
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<td>Anna Pank – Director of International Development, Global Impact and Outcomes at JDRF, New York, United States</td>
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<td>Bernard Charpentier – Chair, Federation of European Academies of Medicine (FEAM) &amp; Science Advice for Policy by European Academies (SAPEA), Belgium</td>
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<td>Coffee break</td>
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11.30 – 13.00  Session 2. How to evaluate the impact of health research?

**Chairs**

Martin Buxton & Stephen Holgate – Members of the Scientific Panel for Health

**Introductory talks**

Koen Debackere – Professor, Faculty of Economics and Business, KU Leuven, Belgium & Network for Advancing and Evaluating the Societal Impact of Science (AESIS), The Netherlands

Kathryn Graham - Executive Director, Alberta Innovates, Canada

Christoph Thalheim - Director of External Affairs, European Multiple Sclerosis Platform, Belgium

**Extended Panel Discussion**

Walter Ricciardi – President, National Institute of Health, Italy

Mairead O’Driscoll – Interim Chief Executive and Director of Research Strategy and Funding, Health Research Board Ireland, Ireland

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**Lunch break**

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13.30 – 15.15  Session 3. How can health research be designed in ways to maximise achieving impact?

**Chairs**

Ildiko Horvath & Dainius Pavalkis – Members of the Scientific Panel for Health

**Introductory talks**

Pierre Meulien – Executive Director, Innovative Medicines Initiative (IMI), Belgium

Ian Viney – Director of Strategic Evaluation and Impact, MRC, United Kingdom

Wendy Reijmerink – The Netherlands Organisation for Health Research and Development (ZonMw), The Netherlands

Stefan Schreck – Head of Unit, Health Programme and Chronic Diseases, Directorate-General for Health and Food Safety, European Commission
Extended panel discussion

Pierluigi Nicotera – Scientific Director and Group Leader, German Centre for Neurodegenerative Diseases, Helmholtz Association, Germany

Stuart Pritchard – Manager, European Union and Public Affairs, Wellcome Trust, United Kingdom

Valerie Mazeau Woynar – Director, Department for Partnerships and External Relationships, INSERM, France

15.15 – 15.45  Break-out session and round-table discussion

15.45 – 16.15  Reporting and wrap up
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<td>Ian</td>
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<td>Bonnie</td>
<td>Science Europe</td>
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