

BRIDGING THE GAP

SUPPORTING LIFE COURSE TECHNOLOGY
DEVELOPMENT AS A CLINICAL-INDUSTRY PARTNERSHIP



Review (AAR)³ clearly sets out the need for a more streamlined approach for technology adoption in the NHS whereby the AHSNs will play an important role in AAR implementation. Importantly, the Life Sciences Industrial Strategy⁴ provides a strong strategic platform to provide focus and investment that will support infrastructure development and collaborations between industry and health to accelerate the development of child health technology.

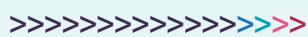
Our work, and that of colleagues, advocates greater need for a life course approach to technology development that focusses on early life. This will ensure that healthcare technology becomes a normal part of healthcare delivery, and that diagnostics and treatment from a young age as well as health-related behaviours are adapted and modified early in life to support effective change. Children and young people in the 21st century are ready for immersive technology within the provision of their care.

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Introduction

The development of technology for children and young people has historically been blighted by two issues. Firstly, technology development has been localised and fragmented, with potentially successful health technology solutions serving small populations with little means of adoption and spread. Secondly, industry has not clearly recognised the need for bespoke solutions for children and the needs for versatile technology that adapts to changing anatomical and physiological needs during growth and development. Thus, there have been many attempts to repurpose technology originally developed for adults with only partial success and with the potential for creating new problems and complications. The development of paediatric technologies has fallen considerably behind the development of technologies supporting adult healthcare, yet the impact of health and healthcare at a young age results in changes that reach far into adulthood. A radical change in the approach to developing healthcare technology for children and young people is required. The Technology Innovation Transforming Child Health Network (TITCH) was established in 2014 to try and address these issues. The network has brought together Specialist Children's Trusts, Specialist Children's Units, AHSNs, NIHR Health Technology Co-operatives (now MedTech and In-vitro diagnostic Co-operatives - MICs) and the NIHR Children's Clinical Research Network to provide a scalable opportunity that allows industry to co-develop technology for children and young people, ensuring appropriate clinician and end-user/family involvement.

Fundamental to the development of technology for the healthcare of children and young people is the need to ensure that the service is ready or can adapt to the new technology, and that there is user-acceptance. There is clear conflict between what works and what works for the patient. While children's healthcare has some excellent examples of technology that has provided benefit to children with health needs, a lot of technology has been rejected because the technology was functionally inappropriate for patients or that it could not be consolidated into the normal daily living of children and young people. Additionally, whilst child health technology may provide a perceived improvement, the service delivering specialist healthcare for children and young people may not be in a position to integrate the technology. For example, face masks for non-invasive ventilation in children were originally scaled down from the adult masks leading to poor fit and the system regularly alarming overnight, impacting on the well-being of family members and resulting in facial pressure sores as masks were tightened to prevent air leakage. Work is underway to provide an innovative solution to address this problem, supported by NIHR i4i. Speaking with children and young people on their needs, in relation to health and long term conditions, revealed a desire to integrate with others, a need to access current trends and to allow them the opportunities accessible to healthy children. In the development of future health technologies for children and young people, due consideration for the needs and desires of end-users need to be consolidated with the needs of clinicians, to develop technology that is fit for purpose and improves quality of life as well as patient health. To facilitate this goal it is important that further technology test-bed facilities are established to assess technology designed solely for children and young people, that are easily adapted to test technology in a hospital or home environment. They should also be versatile enough to accommodate changes in growth, maturity and transition from child to adult care settings.

While there is a clear move to assign transformative designation to technologies that provide a greater magnitude of health gain aligning with unmet need, this may be more challenging in child health giving the relatively diminutive scale of health care issues relative to problems such as stroke, heart disease and dementia. However, there are two factors that must be considered in relation to child health technology. The CMO report, *Our Children Deserve Better: Prevention Pays 2012*², clearly articulates the need for early preventative measures in child health to ensure a healthier adult population and to address

health inequalities early. In addition to this, complications relating to the multiple conditions that start in childhood including type 1 diabetes, epilepsy and asthma, could be reduced during the life course through health management and behavioural change supported by bespoke child health technology. To achieve this goal, a coordinated approach to the development and adoption of technology at scale should be considered, that encompasses multiple centres and clinicians using a national networked approach.

As children with long-term conditions are surviving well into adulthood a transformative approach to the delivery of healthcare is required. The number of children affected by long-term conditions and their associated complications provides a compelling argument for investment in child health technologies to adopt a life course approach to improving the health of the nation.

- Public sector annual costs of preterm birth to age 18 are estimated at £1.24 billion and total societal costs at £2.48 billion (including parental costs and lost productivity)⁵
- 20% of adolescents may experience a mental health problem in a year⁶. 50% of mental health problems are established by age 14 and 75% by age 24⁷ and 10% of children and young people (aged 5-16 years) have a clinically diagnosable mental health problem⁸, yet 70% of children and adolescents who experience mental health problems have not had appropriate interventions at a sufficiently early age⁹. The NHS England Five Year Forward View cites the need to address mental health conditions in children and young people¹
- Over 0.8 million children aged 0–18 in the UK are disabled, accounting for 6% of all children¹⁰.
- Asthma is the most commonly diagnosed long term condition in children affecting 11 million children (1 in 11)¹¹ and has one of the highest emergency admission and death rates in Europe with over 1,000 deaths per year resulting from asthma^{12,13}
- Individually rare diseases are 'rare' but collectively are common. 1 in 17 people will be affected by a rare disease (approximately 3.5 million people in the UK) of which 75% percent affect children¹⁴
- The leading causes of death in children aged 1 to 9 years in the UK include neurological (e.g. epilepsy) and developmental conditions, congenital anomalies, cancer, injuries and complications of pre-term birth. With advanced technology many of these deaths are preventable¹⁵
- Long-term costs of childhood obesity are estimated at £588–686 million^{2,6,16}. By 11 years old 1 in 5 children are obese with over 40% of children being overweight in the most deprived areas of the country. The UK-wide NHS costs attributable to overweight and obesity are projected to reach £9.7 billion by 2050, with wider costs to society estimated to reach £49.9 billion per year¹⁶⁻¹⁹

Children and families more readily access health services due to the increasing complexity in managing long-term conditions. The recent NICE recommendations for transition of care have also resulted in a need for health services to better focus on the care of children with chronic conditions moving into adult healthcare providing an additional but requisite challenge for the delivery of services for young people⁴. The delivery of healthcare in the community and homes provides greater opportunities for children to benefit from education and peer-group integration. Improving the health of children and young people leads to an improvement in educational attainment. One extra year in education increases life expectancy by 1.7 years. Where poor school attendance and poor achievement are present, the risk of ill-health is 4.5 times higher in adulthood²⁰. Thirty-one percent of school pupils aged 11–15 years in 2012 who reported having a long-

- To provide a comprehensive document of funded technology that has and has not been adopted by the NHS to help inform and future-proof technology funding support
- Networks such as TITCH to support companies and industry-academic collaborations in the development of technology applications in paediatric medicine in a similar way to the NIHR RDS
- Explore the potential to implement a staged process to funding calls to allow applicants to introduce outline proposals, and pre-application proposals to save SMEs time in applying for major bids. A rapid turn-around time needs to be applied to this process
- To provide new 'scaling-up' opportunities aligning unmet need to technology development and market access to small 'proven' companies to allow growth of the UK MedTech Sector
- To incorporate healthcare technology development in the undergraduate syllabus for medicine
- To ensure that SMEs are directed to the framework on NHS Intellectual property
- To signpost SMEs earlier to organisations that facilitate technology transfer in the NHS
- Ensure that patients and families are involved at all stages of technology development in the innovation pipeline
- To simplify adoption and commissioning routes through collaborative working between key healthcare organisations supporting the adoption of paediatric technology in the NHS
- To create a national centralised platform for clinicians to submit unmet needs in children and young people. This would be supported by a team who would collate and prioritise needs based upon local, regional national importance, supported by consistency of reporting
- To support a review of technologies that have not succeeded in the NHS despite initial adoption, to develop an understanding as to why some technologies for children and young people do not succeed
- Future technology development for the early life course should clearly demonstrate user-input from an early stage. Organisations such as TITCH, NIHR Children's CRN, NIHR CYP (Children and Young People) MedTech Cooperative, NHTA and AHSNs can facilitate user engagement through stakeholder networks
- A review of current technologies for children is required to identify technology that falls short of requirements for children and young people. Disinvestment in old and outdated technologies should be considered in conjunction with age and developmental specific technologies for children
- To determine areas of uptake and rejection of technologies developed for children and young people following funding including SBRI Healthcare, Innovate UK and NIHR i4i
- Regional patient and family cohorts should be developed to support the co-development, assessment and evaluation of technology across the UK
- The Innovation and Technology tariff should take into consideration age specific need for technology



Challenges faced by industry in accessing and working with the NHS

The goal of the technology adoption in the NHS is to support 'the best technology for best health'. This is particularly important for the younger generation whose behaviour is already heavily technology focused. Managing healthcare with appropriate technology will support new models of healthcare delivery that support better self-management and more rapid access to clinical services from remote locations. There is a need to ensure that the NHS is in a position to rapidly identify technology solutions at low cost, through an effective partnership with industry. Since the publication of Innovation Health and Wealth²², the system has improved significantly in enabling greater engagement with the private sector but delegates at the NHSA/TITCH event felt more could be done within the realm of children and young peoples' health. Facilitating co-creation of technology driven by areas of unmet need in healthcare has the advantage of bringing together experts in technology and digital development with those who have the knowledge of the clinical area and understand the pathways to funding. However, to establish effective partnerships, both industry and clinical academics need to converge on an agreed and acceptable timeframe for technology development and evaluation. A move away from the traditional research cycle of 3-4 years to receive a grant, establish a study and write up, needs to be refined to meet the demands of healthcare. However in contrast, SMEs often wish evaluation to run for 6 months as the technology development cycle is so rapid that new versions may make longer trials useless. At present, models of research evaluation of technology are untenable within the current NHS R&D framework. Thus a middle ground needs to be established by which an appropriate but rapid clinical evaluation process at low cost can be supported to drive appropriate technology evaluation and adoption. NHS R&D departments need to be ready to support this new form of technology development and evaluation in paediatric medicine. This should include all trusts inclusive of primary and secondary care. A comprehensive survey could assess 'technology-evaluation-readiness' of NHS trusts. Importantly one of the other barriers articulated by delegates was the means of being able to procure 'market-ready' technology. The issue of 'falling at the final hurdle' is occurring as individual Trust budget lines are unable to accurately identify good-fit for technology purchasing, nor value long-term health economic outcomes.

Industry partners are aware that public funding is available to support technology development across the innovation pipeline. However, SME partners require clarity on where to find information about these funding streams and how these funding routes are connected. SMEs in attendance cited that the funding routes offered for health-technology development are often complex, opaque and inaccessible. Additionally, the route to funding is often a time-consuming and lengthy process compared to their own internal technology development cycles and thus is not a viable option for most small innovative companies. Smaller companies feel that the odds of achieving research funding in the current climate are too low and will therefore not invest valuable and limited resources in applying. Once technology has undergone development and is market ready, the end goal for SMEs is bringing a product to market to ensure success, generate business and provide further investment to develop their product further and to develop new products. Scalable market access for health technology in the UK requires an access point to the NHS that has the potential to scale. SME's are struggling to determine the appropriate point of access to discuss adoption and procurement and are often met with barriers, or a time-consuming and lengthy process to speak with the most appropriate person to consider their healthcare technology. The consequence is that SMEs look for more accessible routes to alternative markets overseas. The AHSNs have helped to streamline this process but it was felt by delegates that more could be done to specifically support paediatric innovation uptake. Thus a clear and simple document outlining potential access routes to the NHS is required for companies working in paediatric medicine. At a local and regional level commissioners and clinicians need to establish appropriate infrastructure that is receptive

to discussions about technology solutions that align with strategic clinical priorities for children and young people across the life course.

SMEs wish their product to undergo rapid clinical evaluation as this provides evidence that their technology is appropriate for patients and will integrate into the service, beyond the CE marking process. However, achieving ethics and site-specific approval, running a clinical trial and presenting results needs to be refined to accelerate the evaluation process. Moreover, clinical evaluation of technology needs to be at a lower cost to make this an affordable option for industry. Ultimately, facilitating clinical evaluation of novel health technology provides a 'win-win' solution for the NHS and industry, through which the NHS benefits from knowing that a product is fit for purpose, integrates well within a clinical pathway and is user-accepted, and industry partners gain knowledge about the use of their product in a 'real-world setting'. Importantly, early rapid clinical evaluation provides payers with the evidence of technology utility, potential affordability, service impact and user-acceptability, so supporting decisions relating to technology adoption. It is important that the process of technology evaluation is not measured by activity but is outcome driven. The current activities based model is not a measure of success but is a measure of action. Thus the model only accounts for doing rather than succeeding. In turn an outcomes based model should drive the next step of refining technologies to ensure that the innovation process is iterative. The requirement to move to a more iterative outcome-based process needs to be facilitated by rapid adoption to ensure that technology does not become outdated.

There is a wealth of expertise supporting technology development in industry and SMEs, academic institutions, AHSCs, AHSNs and directly within clinical settings. The demand from industry is that they can utilise their expertise to match the areas of unmet need. To do this, industry requires knowledge of the NHS' unmet needs. Whilst in principle this sounds relatively straight forward, there appears to be no centralised means of understanding the paediatric technology needs for the NHS. Regional efforts have been established such as the MIMIT (Manchester: Improving Medicine with Innovation and Technology) model in Manchester but centralised access to NHS unmet needs remains unavailable. Commissioned technology calls are often relatively open-ended; Industry partners require direction to understand the needs of specialties such as child health in the NHS, and an access point to explore those needs. This may not necessarily be a single access point but could be set out as a 'road-map' to direct industry to the most-pressing technology needs in the NHS. In turn technology expertise can be applied to developing solutions which in turn could result in rapid evaluation and adoption, leading to a positive impact on children's healthcare. The clear challenge is to develop a system that is efficient in identifying and defining those needs with the children and their parents and carers.

technology, materials science, 3D technologies, engineering and design. Without this knowledge, clinicians are stifled in identifying areas of unmet needs that may be amenable to technology solutions. This has already been trialled at Sheffield Children's Hospital and Sheffield Hallam University. By academics presenting the advances of technology and science in specific areas, clinicians were able to think of ways in which their practice could be improved and enhanced, thus supporting new collaborations, research and novel technology development. It is imperative that clinicians are educated in the broader opportunities in science and technology to generate new advances where unmet needs were not previously realised. There needs to be a cultural shift in the NHS organisations to foster a more creative, inventive and innovative culture; in-turn new collaborations will develop. This process must start from undergraduate level to ensure a new generation of doctors who understand the opportunities for new technology development, and realise the potential to radically evolve healthcare in the UK – a process of 'building young minds for future healthcare'. Those planning undergraduate courses for medicine should consider incorporating health technology development into the undergraduate syllabus. In turn a creative, inventive and innovation culture becomes embedded in healthcare organisations.

Intellectual Property (IP) has become a contentious area in industry-NHS-academic relationships. SMEs are dependent on the IP developed and subsequent licensing as a means of future revenue streams. Industry feels that the IP relationships with the NHS and academic partners are often complex and rarely benefit SMEs. Given the risk to companies, SMEs are reluctant to work directly with NHS and academic partners unless a transparent and equitable intellectual property system is established. Conversely, in a rapidly expanding technology and innovation landscape, health and academic institutions are fiercely protective of IP. Guidance issued by the NHS National Innovation Centre is already in place to support NHS trusts in establishing IP arrangements with industry. This guidance should be cited in funding calls and by NHS Trusts early in the development of partnerships with SMEs. Trusts should support flexibility to negotiate IP arrangements with companies at an early stage to encourage technology development with IP arrangements that benefit all parties. Partners in technology development should also realise the benefit and support provided by technology-transfer organisations.

As expected, technology solutions for the NHS and in particular children's healthcare are striving for return on investment and value for money. Ultimately the end-user is fundamentally the most important person in the technology pipeline. While the drive for rapid technology development is important, failure to involve patients and their families in the development or evaluation of technology often results in technology failure. There are numerous examples where technology has entered 'the valley of death' as it has not been accepted by the end-user or cannot be appropriately integrated into a clinical service. The innovation pipeline starts at unmet need and proof-of-concept and ends with diffusion and adoption. However 'acceptance' and 'review' need to be added to the end of the pipeline to ensure that child health technology is well-integrated into the appropriate healthcare setting, is acceptable to users and to then establish the need for improvement. The drive for industry to sustain an effective business model and income stream, and the high-demands of the NHS to develop novel solutions must be tempered by the need to involve end-users to ensure the 'best technology for best health'. Clinicians need to consider the differences between perceived and real risk to the implementation of technology solutions. Implicit in this statement is the focus on the requirements of the clinician which may extend beyond the bounds of the technology capability. Inappropriate clinical demands on SMEs will prevent good technology from benefiting the end-user. Over-ambitious clinical expectations should not hamper the adoption of technology that ultimately benefits patients and provides a more effective means of healthcare delivery.



Recommendations

- To incorporate healthcare technology development in the undergraduate syllabus for medicine
- To ensure that SMEs are directed to the framework on NHS Intellectual property
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A focus on technology for child health - a start to the life course approach

On a day-to-day basis, paediatricians identify problems, but often perceive the development of solutions as time consuming or insurmountable. Because of this, problems in healthcare persist occasionally through generations of doctors. It is highly likely that many of these issues are common to multiple healthcare organisations. A centralised means of collecting and communicating these issues should be considered. This would provide a unified approach for clinicians to report issues they face and to define unmet need at scale. Centralised processing and prioritisation of these issues could lead to a repository of unmet needs that could be accessible to industry on a national open platform. It may also drive a commissioned focus on technology development. There is a clear need to align local, regional and national strategic priorities with the development of technology, but also for these to be considered in the wider scientific community to understand whether technologies used in other areas of the life sciences industry can be modified for the benefit of healthcare through the life course. The wider life sciences community often approaches healthcare issues with an understanding of the technology available rather than the healthcare need, adding a fresh perspective. Local, regional and national collaborations should be encouraged to ensure that clinical unmet needs are validated and shared to ensure that the latest technology is applied to meet these healthcare needs.

While areas of children's healthcare innovation have received much-needed policy support, and investment from groups such as SBRI Healthcare, NIHR i4i and Innovate UK, more widespread support and policy change for innovation in child health across the UK remains relatively unstructured and fragmented and requires additional significant investment. The development of technology to support children and young people has the clear advantage of supporting health through the life course. This includes an approach to preventing ill health in a healthy population of children, to minimise the impact on adult health issues, for example co-morbidities in relation to childhood obesity. Many of the adult diseases causing a significant health and economic burden have their origins in childhood. In the last few decades we have seen a significant rise in child and adult obesity, with a concomitant rise in the metabolic complications that includes heart disease, stroke and heart disease. Coronary heart disease results in 73,000 deaths each year²⁴, and over 2.1 million people under the age of 45 had high blood pressure in England in 2015²⁵. More than 100,000 people per year have a stroke²⁶, deaths from chronic liver disease have risen by 20% in the last decade in part due to the rise on obesity and alcohol consumption²⁷, admissions to hospital for non-alcoholic fatty liver disease (NAFLD) have risen 12-fold²⁸, and it is estimated that by 2030, 4 million people in the UK will have had a form of cancer²⁹. Unhealthy lifestyles have their origins in childhood and are a major contributing factor, as these diseases are precipitated by obesity, poor diet, smoking and increased alcohol consumption. In 2015, 63% of adults were overweight or obese resulting in an estimated £5.1 billion spend on overweight and obesity related health disorders and a further £27

billion cost to the wider society¹⁹. Ironically the historical focus in trying to deal with these issues has started in late adulthood. However, there is clear evidence to demonstrate that to prevent unhealthy lifestyles and to minimise the risk of the disease, intervention in childhood is required. Novel technologies to support health prevention strategies used in primary care and education could fundamentally address these issues.

There is a clear desire from children, their families and clinicians to support the health of children with chronic conditions in the home and community to minimise the number of attendances in hospital and to prevent the escalation of complications which in-turn will reduce the number and length of in-patient admissions. Technology can also support health education for children and their families to manage acute episodes of disease and to reduce unnecessary GP and emergency department attendances. It was felt that TITCH, alongside organisations like the NHSA, could play a role in helping to streamline different sources of investment and influence national policy to enable children faster access to technology. Organisations such as TITCH have and will continue to link industry with children and families to help industry to understand patient needs in relation to current technology development and to understand areas of unmet needs. Industry partners have clearly expressed their desire to work with young people and their families to ensure that the technology they develop is fit for purpose. In the planning of future early life course technology, stakeholders should support patient and family inclusivity.

Historically, healthcare technology for children has been repurposed from adult technologies with variable success. To address this issue and to identify areas of improvement, a review of current technology used for children is required to determine areas where technology for children and young people is not achieving desired outcomes, or is resulting in unnecessary complications. This should catalyse a new wave of technology co-development that involves industry, clinicians, engineers, designers, patients and their carers to drive innovation that delivers the best healthcare outcomes. This will in turn drive sector growth in this niche area, founded on the need to start early in the life course to support the future healthcare of our population. This will ultimately position the UK as a world-leader in the development of technology for children and young people.



Recommendations

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- To support a review of technologies that have not succeeded in the NHS despite initial adoption, to develop an understanding as to why some technologies for children and young people do not succeed
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A summary of workshops held in April 2017
hosted by the NHSA and TITCH