Health Services Safety Investigations Body

## Investigation report

# Insulin: supporting safe self-administration for patients in the community – inequalities in technology and access to care

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Mental health, Medication, Learning disabilities

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## A note of acknowledgement

The investigation team would like to thank the many people who contributed to this investigation series. Patients, families, carers and staff shared their personal experiences with us, including intimate and traumatic situations.

## About this report

This report is the fourth and final report in a series considering the self-administration of insulin by adults with diabetes mellitus (diabetes) in community settings. Each report in the series focused on specific groups of people who, due to their circumstances, may be at increased risk of harm because of the way they self-administer insulin. This report brings together shared learning from across the series and makes further safety recommendations.

Appendix 1 to this report links to the findings and safety recommendations from the three previously published reports and provides an update since their publications. The previously published reports were:

- Insulin: supporting safe self-administration for patients in the community with a mental health problem
- Insulin: supporting safe self-administration for patients in the community with a disability
- Insulin: supporting safe self-administration for patients in the community with a learning disability

These reports also contained safety learning via safety observations, suggestions for integrated care boards, and local-level learning for provider organisations.

The terminology used in this report has been chosen while acknowledging that there are differing views across organisations and groups. The report refers to ‘patients’ in line with NHS documents and people with a ‘mental health problem’ in line with Mind (2017). It also refers to people with a learning disability but with recognition that the term ‘intellectual disability’ is being increasingly used (National Institute for Health and Care Excellence, 2015). A glossary of terms is provided in report 1 of this series, and additional terms are described in this report.

# Executive summary

## Background

This is the fourth and final report in a series considering the self-administration of insulin by people with diabetes mellitus (diabetes) in community settings. This report focuses on the availability and design of diabetes technologies and insulin pen devices. It also shares findings from across the series of investigations and identifies learning to inform strategic plans for supporting patients in community settings. It should be read in conjunction with the previous investigations in the series.

Many people with diabetes administer their own insulin to manage their blood sugar levels, either by injection or using an insulin pump. However, a disability or impairment may affect someone's ability to safely administer their own insulin if they are not supported. This can lead to short-term and long-term health problems, which can be life threatening.

Across this series of investigations, HSSIB identified patient safety incidents in which people with diabetes requiring insulin, who also had disabilities or impairments, were harmed when they were not supported to administer their insulin safely.

### Findings

- Diabetes technologies, such as combined glucose monitoring and insulin pump systems – which can be combined in a hybrid closed loop system – can support patient safety and wellbeing, but access to these is variable and inequitable. Difficulties accessing technology faced by people with conditions such as a learning disability could be exacerbated by current implementation plans.
- Workforce capability is not keeping pace with the adoption of diabetes technologies. Community and non-specialist staff are increasingly encountering patients using diabetes technologies, but report they have limited confidence, training and support to help them care for these patients.
- Some patients described choosing to use do-it-yourself closed loop systems for their insulin management, in some cases due to difficulties accessing technology on the NHS. These systems are unregulated in England and no supporting guidance is available for the NHS.
- The design of insulin pen devices does not always support safe use by people with disabilities or impairments. There are gaps between manufacturers' assurance of user-centred design and the real-world experiences of patients and staff.
- There is limited guidance to help staff match insulin pen devices to individual patient needs. Staff may not have enough accessible information about which devices are best suited to people with visual, dexterity, cognitive or memory-related needs.

- People with diabetes, who self-administer insulin and have co-existing disabilities or impairments, are at risk of harm where they are not supported to safely manage their care in the community.
- Specialist diabetes care provision, and collaboration with other services, varies across the country; there is limited clarity on future national plans to manage the risks this variation creates for patient safety.
- Living with various disabilities – including a mental health problem or learning disability – affects access to diabetes care and diabetes technology, and the safe use of insulin pen devices. Evidence of potential discrimination was also found in relation to disability and age.
- Fluctuating mental capacity to make decisions about insulin self-management was repeatedly seen to contribute to patient harm. Proactive safety planning for when a person may lose capacity was limited.

**HSSIB makes the following safety recommendations**

**Safety recommendation R/2026/099:**

HSSIB recommends that NHS England/Department of Health and Social Care develops guidance that supports the ongoing implementation, provision and management of diabetes technology, including hybrid closed loop (HCL) systems. This guidance should:

- be informed by the evaluation of real-world data around uptake and impact of the roll-out of diabetes technology to date
- consider both the benefits and risks associated with HCL systems for patients with different and multiple needs – including cognitive, sensory, physical and mental health needs – and disseminate learning on where HCL systems have been effectively implemented for these patient groups
- seek to support collaboration across organisations to identify educational opportunities and resources to build the capability of the healthcare workforce in relation to diabetes technology.

This is to support long-term provision and wider implementation of diabetes technology in a safe, effective and equitable way.

**Safety recommendation R/2026/100:**

HSSIB recommends that the Medicines and Healthcare products Regulatory Agency – through their oversight of Approved Bodies – ensures conformity assessments promote comprehensive assessment of insulin-related medical devices that:

- consider the needs, characteristics and capabilities of diverse user populations, including people with protected characteristics, and the potential impact of device design on equitable access, usability and safety for the intended user
- identify, assess and mitigate risks associated with intentional and unintentional misuse, including situations where a person's physical, cognitive or mental health needs may affect the safe use of a device.

This is to support the safety of the diverse range of people who administer insulin, and to promote the development of devices that better recognise and mitigate risks associated with insulin administration.

**Safety recommendation R/2026/101:**

HSSIB recommends that the Association of British HealthTech Industries and the Association of the British Pharmaceutical Industry facilitate the engagement of manufacturers with healthcare and people with lived experience to inform inclusive and user-centred design of insulin pen devices based on the findings of this investigation. This is to ensure that insulin pen devices meet the diverse needs of users and address risks associated with the task of insulin administration.

**Safety recommendation R/2026/102:**

HSSIB recommends that NHS England/Department of Health and Social Care, working with integrated care boards, develops specifications for community and home-based diabetes care to address gaps in collaboration between provider organisations that impact on the safety of patients. This should include consideration of the:

- availability of, and access to, specialist diabetes services in community settings
- shared care arrangements between specialist diabetes, mental health (including specialist eating disorder), learning disability, and general practice services
- capability and capacity of services to care for the increasing number of people with diabetes and the use of diabetes technologies

- identification of, and ways to address, disparities in access to care, and removal of disadvantages experienced by people with protected characteristics.

This is to support a co-ordinated approach to diabetes care, such as through Neighbourhood Health plans, to enable services to safely and effectively care for people with diverse cognitive, physical, sensory and mental health needs.

**HSSIB makes the following safety observations**

**Safety observation O/2026/095:**

Organisations and individuals can improve patient safety by ensuring misuse – including deliberate self-harm – and abnormal use of diabetes technologies and insulin pen devices are reported to the Medicines and Healthcare products Regulatory Agency via their Yellow Card reporting site.

**Safety observation O/2026/096:**

Approved and Notified Bodies can improve patient safety by ensuring that insulin-related medical devices meet the needs, characteristics and capabilities of diverse user populations, including situations where a person's physical, cognitive or mental health needs may affect the safe use of a device. Design should also consider how to reduce misuse of insulin pen devices and the potential for deliberate self-harm.

**Safety observation O/2026/097:**

National organisations with responsibilities for supporting the care of people with diabetes – in collaboration with pharmaceutical companies – can improve patient safety by providing evidence-based guidance to the healthcare system on the design of different insulin pen devices and the patient needs – such as dexterity or cognitive – they are best suited for.

**Safety observation O/2026/098:**

Organisations involved in the provision of clinical undergraduate and postgraduate education programmes, and trust preceptorship/induction programmes, can improve patient safety by using the findings of HSSIB's investigations to prioritise diabetes care and insulin management education and training as appropriate, with coverage including the risks that the use and misuse of insulin can present for patients with a mental health problem.

**HSSIB suggests safety learning for integrated care boards**

HSSIB investigations include safety learning for integrated care boards where this may help organisations think about how to respond to a patient safety issue that relates to integrated care across a geographical footprint. Informed by the findings in this report, the investigation proposes the following safety learning.

**Safety learning for integrated care boards ICB/2026/024:**

HSSIB suggests that integrated care boards, through implementation plans for modern diabetes technology – including hybrid closed loop systems and continuous glucose monitors – proactively seek to reduce inequitable availability for their local populations who would safely benefit from these technologies.

**Local-level learning**

HSSIB investigations include local-level learning where this may help providers/organisations respond to a patient safety issue at the local level. Informed by the findings in this report, the investigation shares the following local-level learning.

- How does your organisation ensure staff who are likely to be caring for patients who use diabetes technology have the required knowledge and skills to support patients to manage their technology safely?
- How does your organisation support staff to explore how a patient's disability or impairment may influence their ability to use an insulin pen device or diabetes technologies?
- Does your organisation have resources to support prescribers to know which insulin pen devices are suited to patients with different disabilities or impairments?

- How does your organisation ensure staff are aware of their responsibilities to report incidents associated with diabetes medication, devices and technology, including to manufacturers and the Medicines and Healthcare products Regulatory Agency?

# 1. Background and context

This report is the fourth and final in a series considering the self-administration of insulin by people with diabetes mellitus (diabetes) in community settings. This section provides background to the topics discussed. Broader background information about diabetes and insulin are available in report 1 (section 1).

## 1.1 Diabetes mellitus and insulin

1.1.1 Diabetes mellitus (commonly referred to as 'diabetes') is a condition where the level of sugar in a person's blood is too high. The body normally controls blood sugar levels through the production of the hormone insulin by the pancreas, but this ability is lost in diabetes. In type 1 diabetes, the pancreas does not produce sufficient insulin and so people will need lifelong insulin therapy. In type 2 diabetes, the body does not produce enough insulin or the body's cells become resistant to insulin and the person may need insulin therapy.

**Insulin and patient safety**

1.1.2 Insulin is a time-critical and high-risk medication. Early or delayed administration can cause harm or reduce its effectiveness (Specialist Pharmacy Service, 2025), and it can cause harm even if used as intended (NHS England, n.d.a). Insulin-related patient safety incidents are common and persistent across healthcare. HSSIB (2025a; 2025b; 2026a; 2026b) has considered insulin-related incidents in acute hospital settings and on discharge of patients from hospital, and in community settings where a patient may have a co-existing disability or impairment.

1.1.3 The wide range of insulin types, devices and regimens is recognised to pose a risk to patient safety because it increases the potential for incorrect selection and administration (Lange Ferreira et al, 2025). To help mitigate this risk, there is national advocacy for people to self-administer insulin when they are able to do so (for example Care Quality Commission, 2016; Getting It Right First Time, 2020).

**Self-administration of insulin**

1.1.4 When safe to do so, supporting a person to administer their own medication is an example of person-centred care. Person-centred care is where healthcare staff support a person to develop the knowledge, skills and confidence to effectively manage their own health (The Health Foundation, 2014). Effective person-centred care supports people's independence, quality of life and positive outcomes (Giusti et al, 2020). In addition, when people take responsibility for their health, this reduces pressure on healthcare services.

1.1.5 Insulin can be administered by subcutaneous injection (an injection under the skin), commonly with an insulin pen device, or via an insulin pump (see 1.2.2) (Diabetes UK, 2025a). A person's family member or carer may also be trained to administer insulin. The vast majority of insulin administration in community settings is done by the patient with or without support from a family member/carer. Insulin administration involves many considerations, as incorrect administration can result in complications and harm. These considerations were explored in report 1 (section 1.2) (Diabetes UK, 2025b).

1.1.6 Self-administration of insulin has many benefits. It can empower the person, provide them with control, and support their independence (Specialist Pharmacy Service, 2023). A person in control of their own insulin management can also ensure they self-administer at the correct time and can adjust the dose depending on their blood sugar levels. This can support better management of their blood sugar levels and reduce the risk of both short- and long-term diabetes-related complications (see report 1, section 1.1).

## 1.2 Diabetes technology and devices.

1.2.1 Insulin can be administered by subcutaneous injection, commonly with an insulin pen device or insulin pump. Insulin pen devices are produced by a range of manufacturers and the choice of pen device is based on compatibility between insulin and device, and individual patient requirements and preferences.

1.2.2 Diabetes technologies are device and software combinations that people use to monitor blood sugar levels, manage their insulin administration, and support their self-care. Diabetes technologies include:

- Continuous glucose monitors (CGMs) – allow the checking of sugar levels without the need to undertake a finger-prick test. CGMs send information to a mobile/reader device, and can provide intermittent or real-time readings. The National Institute for Health and Care Excellence (NICE) (2022a; 2022b; 2023a) provides recommendations on who should be offered CGM.
- Insulin pumps – an electronic pump that releases insulin into the body through the day and night. Insulin rates can be adjusted based on need, such as depending on how active the person is.

- Hybrid closed loop (HCL) systems – involve a pump and CGM ‘talking to each other’ to automatically adjust the insulin dose (Diabetes UK, 2025a). NICE (2023b) recommends which patients should be offered HCL systems as an option on the NHS and, to support implementation, NHS England (2024) has published a 5-year strategy.
- Smart insulin pens – some insulin pens have functionality that automatically records when insulin has been administered and the dose given. They may also display the time since the last injection (Diabetes UK, 2025c), and connect to apps that combine data from blood glucose meters and CGMs

### 1.3 Patient safety context

1.3.1 This series of investigations was launched in response to evidence of repeated patient harm associated with the self-administration of insulin. The findings identify gaps in care at national, regional and local levels. Until these gaps are addressed, risks to patients will remain.

1.3.2 These patient safety risks are likely to affect increasing numbers of people. Reports in this series have described harm involving people with a range of disabilities and impairments, including mental health problems. Diabetes prevalence is rising, with an estimated 4.3 million people expected to be affected by 2030 (NHS England, n.d.a). Evidence also suggests that population mental health is deteriorating and that people are living longer with increasing levels of disability and impairment.

## 2. Analysis and findings – diabetes technology and devices

This section describes the investigation’s analysis and findings in relation to access to diabetes technology and devices, informed by previous reports in the series. Access includes availability (the ability to have the technology/device) and design (the extent to which the technology/device can be used by people).

Various forms of diabetes technology and devices were encountered during the series, most commonly continuous glucose monitors (CGMs), insulin pen devices, and hybrid closed loop (HCL) systems. Access issues with technology and devices had caused or had the potential to cause harm to patients.

### 2.1 Availability of diabetes technology

2.1.1 Evidence shows that some diabetes technologies can improve long-term patient outcomes. These technologies can also reduce the risk of acute diabetes-related complications and lessen the distress associated with managing diabetes (Crabtree et al, 2023). For patients who may benefit from technologies, limited availability can therefore create risks to their safety.

2.1.2 HSSIB's investigations identified examples where technology had not been made available to patients who may have benefited from it. These included the availability of HCL systems for eligible people with a mental health problem (see report 1, section 4.2) and people with a learning disability (see report 3, section 3.1).

2.1.3 The investigation was told by patients, clinicians and national stakeholders about variation in the availability of diabetes technology for adult patients who have a disability or impairment. While technology will not be appropriate for every patient, "discrimination" against some was described. Several factors that influenced availability were identified. These included:

- assumptions that people would not be able to use a particular technology
- limited engagement with those who would benefit but who, due to their circumstances, were not able to actively seek it out
- workforce capability and reluctance to engage with modern technology
- a "postcode lottery" depending on where someone lived in England
- limited national funding to support reimbursement of organisations for the supply of HCL systems.

2.1.4 The investigation heard about a "postcode lottery" in relation to smart insulin pen devices, CGMs and HCL systems. Postcode lottery is a term used to describe unequal provision across different geographical locations, in this case availability of technology provided by the NHS. National stakeholders said that unequal provision exists due to national resourcing constraints and devolution of decisions to integrated care boards (ICBs); these factors have led to unwarranted variation based on local interpretation of guidance and population needs.

**Continuous glucose monitors**

2.1.5 NICE (2022a; 2022b) provides recommendations on which people with diabetes should be offered CGMs. Figures suggest that, on average, around two-thirds of eligible patients with type 2 diabetes use a CGM (based on NHS England (n.d.b) data). The investigation heard from national stakeholders that successful uptake was due to the clear eligibility criteria for CGMs, evidence of benefit, and national promotion.

2.1.6 Despite the high uptake and evidence of benefit, the investigation saw variability in the provision of CGMs across the country. Differences in provision have been reported in relation to geography, levels of deprivation, age and ethnicity (NHS England, n.d.b). The investigation was told that differences were contributed to by ICB decisions on local formulary criteria for CGMs, the allocation of resources for the implementation of technology, and whether implementation recognised and adjusted to needs or differences across their populations. For example, the investigation heard that areas with high deprivation had high levels of digital exclusion and,

without support, patients in these areas were less able to access and effectively use technology. Systemic barriers to accessing care for people from particular ethnic backgrounds were also heard to impact on access, and this has been reported in research (Seidu et al, 2025).

2.1.7 No specific data could be found on provision and uptake of CGMs among patients from cohorts explored in this series of investigations – that is, people with a learning disability or people with a mental health problem. The findings in this section have contributed to the learning for ICBs in 2.1.35.

**Smart insulin pens**

2.1.8 The investigation heard how smart insulin pens (see 1.2.2) may benefit people with certain disabilities, such as people with memory impairment who require prompting to remind them to self-administer. The investigation did not observe patients using smart insulin pens, but heard how they may be of benefit. While some of these pens were advertised as available on the NHS, the investigation heard from clinical staff that they were rarely prescribed.

2.1.9 National stakeholders described how, in contrast to CGMs, there was no NICE guidance on eligibility for smart pens and limited national promotion. This meant awareness among prescribers was limited, and several prescribers engaged with did not know whether they could be prescribed.

2.1.10 NICE confirmed that it had not undertaken work in relation to smart pens and that this subject had not been raised with NICE to date. The investigation also observed that in some areas, local formularies (which set out what can be prescribed in an area) did not include smart pens; staff said that due to cost, ICBs had not always made them available.

**Insulin pumps**

2.1.11 The investigation met patients who believed they were eligible for an insulin pump, in line with national guidance, but had not been offered one. Specialist diabetes clinicians have also described unwarranted variation in availability (Iacobucci, 2019). The investigation was told that patients who may benefit most from these technologies, because they have existing challenges managing their blood sugar levels, may not receive them because of issues with availability and design.

2.1.12 From an availability perspective, NICE (2023b) recommends which patients should be offered HCL systems as an option on the NHS. To support implementation, NHS England (2024) published a 5-year strategy to ‘ensure equitable and fair access’. The strategy described the role of ICBs in implementing HCL systems, with initial roll-out planned for ‘type 1 diabetes patients where the need is greatest and to those who are likely to benefit the most’. This

included children and young people, people who are pregnant or planning pregnancy, and adults already using a pump who want to move to an HCL system. NHS England contributes to the costs of HCL systems.

2.1.13 Clinicians working in specialist diabetes care described the importance of making HCL systems available to patients who would benefit from them. They recognised that the NHS England (2024) implementation strategy was a step towards this. However, they also highlighted issues relating to limited funding for adult patients, uncertainty about long-term funding beyond the 5-year strategy, and the expectation that responsibility for sustained funding, including when patients transition from child to adult services, would fall to ICBs. ICBs told the investigation about their financial constraints and concerns about supporting patients in the long term.

2.1.14 Clinicians working in general practice and specialist diabetes care also described concerns that, while the intention of the national implementation strategy was to avoid the ‘exacerbation of existing health inequalities’, it was “inevitably exacerbating inequalities” in adult populations and would continue to do so. They said this was because the criteria excluded patient groups who had already experienced exclusion, and because limited long-term funding created a barrier to wider implementation. They further highlighted that, even if funding was available to support equitable availability of HCL systems, the capacity, capability and attitudes of some healthcare providers to safely and effectively support patients with varying needs were underdeveloped.

2.1.15 Specific to people with a learning disability, the investigation heard views at local and national levels that it was “too difficult” for people to self-manage with an HCL system because it requires numeracy and literacy skills, and the ability to manage complications. The investigation was also told that national work to consider HCL systems for eligible people with a learning disability had not progressed because it had been assumed that patients would not be able to acquire the necessary skills.

2.1.16 In contrast, the investigation engaged with specialist diabetes services that had supported people with learning disabilities and/or mental health needs to self-manage their diabetes using an HCL system. These services took a risk-based approach, recognising that for some patients the risk of harm from incorrect use of the HCL system was greater than the risk of not having one. Where services assessed that they could support patients to benefit from HCL systems, an individualised care plan was developed. They emphasised the need for a strong social support network, training adjusted to individual needs, and regular access to specialist support.

2.1.17 Specialist diabetes services also described the resource-intensive nature of supporting someone with complex needs to manage an HCL system safely and effectively. For some patients, intensive daily support was required. Services recognised that they did not have the resource to provide this level of support for everyone and that, in practice, they had to prioritise patients who were able to self-manage with limited support. Clinicians called for national bodies either to provide the resource required to build capacity and capability, or to give clear national messaging about limitations in NHS resources and the inequalities this creates.

2.1.18 The investigation met with NHS England to explore longer-term plans for the implementation of HCL systems. NHS England described a potential need for ICBs to continue implementation and ongoing provision of HCL systems, possibly without continued central funding because of the finite availability of funds. It also described the need for evaluation data to enable ICBs to develop business cases that justify investment in HCL systems based on their benefits. At the time of writing, paediatric evaluations were planned and efforts were ongoing to secure funding for an adult-focused evaluation.

2.1.19 Regarding wider implementation of HCL systems for patients beyond the cohorts described in the 5-year implementation strategy, NHS England recognised the benefits these systems could offer to people with a learning disability and/or mental health problem. However, it echoed findings in this and previous reports that HCL systems could also introduce other risks to patient safety if patients were not supported on an individualised basis, with safeguards in place to support safe and effective use.

2.1.20 NHS England was also aware of variation in prescribing HCL systems to patients with different needs and in different parts of the country. It highlighted the need for ICBs to understand their local population needs, and for better sharing of examples about where barriers to wider implementation of HCL systems had been overcome. In support, a Health Innovation Network (HIN) (2026) national transformation programme has also been established and has produced a toolkit aimed at NHS regional teams, integrated care boards and provider organisations. The findings in this section have contributed to the safety recommendation in 2.1.34 and learning for ICBs in 2.1.35.

**Workforce competence and confidence**

2.1.21 A further factor identified as influencing the availability of HCL systems was the competence and confidence of the workforce. This has also been described by researchers (Kelly et al, 2025). Lack of confidence referred to specialists' confidence to make risk-based decisions to prescribe HCL systems, and non-specialists' confidence in their ability to support patients.

2.1.22 The investigation observed the role of community nursing teams (CNTs) in supporting patients with diabetes in the community. As the number of patients with CGMs and HCL systems grows, CNTs are increasingly supporting patients with these technologies. However, the CNTs engaged with described “fear”, that they “wouldn’t touch” an HCL system, and that they had not received appropriate education (see report 2, section 2.3).

2.1.23 All those engaged with fully supported that only trained and competent staff should prescribe, initiate and support a patient to maintain an HCL system. However, they described unclear expectations for non-specialist staff, a lack of awareness education for the wider workforce who will encounter patients with diabetes technology, and a lack of “future proofing” for patient safety as the number of patients with HCL systems increases. At the time of the investigation, 12% of eligible adults and 76% of eligible children and young people (0 to 18 years) had an HCL system (NHS England, n.d.b). This was described by one patient as an “avalanche” of need coming towards adult services without a workforce ready to manage it. Kelly et al (2025) have also described a ‘growing gap’ between workforce confidence and formal training.

2.1.24 In response to the need to build workforce capability, various case studies were seen where collaboration between community nursing and diabetes services had successfully established patients on HCL systems (for example, Hards, 2026). A national competency framework for diabetes technologies, including HCL systems and CGMs, was also published in July 2026 (Richardson et al, 2026), with an accompanying self-assessment competency tool (DTN UK, 2026). The framework contains four levels for targeting different audiences; for example, level 2 is targeted at healthcare professionals who require competence to support basic management decisions and practical care.

2.1.25 NHS England confirmed that it was not involved in supporting the implementation of formalised training around HCL systems and CGMs in line with the national competency framework. It recognised the importance of training but described barriers to nationally mandating training (see 3.3.3). It further described the role of professional societies in providing training. The findings in this section have contributed to the safety recommendation in 2.1.34.

2.1.26 NHS England also confirmed that it was developing a national career and core capabilities framework for adult community nursing. This will give attention to long-term conditions and will consider how to reflect awareness of diabetes technology and insulin safety, in line with the national competency framework. General practice nursing already has a national career and core capabilities framework, which offers similar.

**Do-it-yourself insulin systems**

2.1.27 During exploration of the availability of HCL systems, the investigation heard about the use of do-it-yourself (DIY) closed loop insulin systems. These are systems that people with type 1 diabetes build themselves using open-source information. The investigation heard that their use had increased because of the availability of open-source information and limitations in the availability of HCL systems via the NHS in England. The investigation was not able to find official figures for the use of DIY systems because there is no official registry. A paper from Breakthrough T1D (2019) suggested that, at that time, over 100 people in the UK were active users.

2.1.28 DIY systems are unregulated, not available on the NHS, and NICE guidance does not refer to them. Various national charities have published position statements around DIY systems, recognising that people have the right to choose treatments that best fit their needs and that they should be supported if they choose to use them. Additionally, Diabetes UK has published recommendations regarding DIY systems (Dowling et al, 2020) and an international consensus statement has been published (Braune et al, 2021). That consensus statement identified real-world data suggesting treatment with these system can be a safe and effective option.

2.1.29 The investigation did not identify incidents relating to DIY systems reported to the Learn From Patient Safety Events service (January to July 2026). However, due to limitations in reporting associated with medical devices (see report 1, section 4.2), this does not mean incidents have not occurred. The investigation heard both support for DIY systems (from patients) and concerns about their use (from healthcare staff). Concerns were around the danger of complications if systems did not function appropriately, and the lack of regulatory assurance of systems and their open-source information.

2.1.30 National stakeholders recognised that the limited availability of HCL systems for some patients (see 2.1.13) may influence personal decisions to use DIY systems. This was confirmed by the small number of patients with DIY systems the investigation met, who described this as a reason for turning to these systems. These patients described how they had benefited physically and mentally from having a DIY system, and felt in control of their insulin management.

2.1.31 NHS England told the investigation that it did not have national work underway or planned in relation to DIY systems. No supporting guidance for NHS staff who may be required to care for patients who use these systems was found. The investigation did not further examine safety associated with DIY systems due to limited available evidence. However, the investigation heard from patients that, if availability of HCL systems is a challenge, more people may turn to DIY systems and the NHS's position in relation to DIY systems needed to be clear; this finding is therefore relevant to supporting implementation of HCL systems as per the recommendation in 2.1.34.

**Summary and learning**

2.1.32 The diabetes technologies considered in this section have been shown to benefit patient safety from both physical and psychological perspectives. However, the investigation found unwarranted variation in the availability of diabetes technology for all patients who may be eligible and may benefit from it. This variation was influenced by national, regional and local factors.

2.1.33 The investigation also found evidence of inequitable availability of diabetes technology for some patient groups. The Equality and Human Rights Commission (2024) is clear that organisational policies must ensure they do not disadvantage people with protected characteristics. No data was found on the availability of diabetes technology for people with a learning disability or mental health problem, but stakeholders told the investigation that these groups “missed out”. At the time of writing, there had been no national evaluation of equity of access to HCL systems across different NHS regions to identify variation; the investigation understands that this is intended.

2.1.34 The investigation recognises that technologies will not be suitable for all patients and that, at the time of writing, the 5-year strategy for the implementation of HCL systems was only at its midpoint. The investigation also recognises that central funding is limited and that ICBs have a role in supporting ongoing implementation and provision. However, HSSIB has highlighted in recent reports that ICBs face challenges ensuring the needs of their populations are met. These challenges relate to changes in how ICBs function and are structured, reductions in workforce including in clinical advisory roles, and financial constraints. These factors have the potential to limit future provision and wider implementation of HCL systems in a way that supports equitable access.

**HSSIB makes the following safety recommendation**

**Safety recommendation R/2026/099:**

HSSIB recommends that NHS England/Department of Health and Social Care develops guidance that supports the ongoing implementation, provision and management of diabetes technology, including hybrid closed loop (HCL) systems. This guidance should:

- be informed by the evaluation of real-world data around uptake and impact of the roll-out of diabetes technology to date
- consider both the benefits and risks associated with HCL systems for patients with different and multiple needs – including cognitive, sensory, physical and mental

health needs – and disseminate learning on where HCL systems have been effectively implemented for these patient groups

- seek to support collaboration across organisations to identify educational opportunities and resources to build the capability of the healthcare workforce in relation to diabetes technology.

This is to support long-term provision and wider implementation of diabetes technology in a safe, effective and equitable way.

2.1.35 At ICB level, the findings demonstrate gaps in understanding of population needs and uptake of technologies. Without this knowledge, commissioning decisions may be affecting the availability of technology to patients, and will also limit the information available to support national decisions.

**HSSIB suggests safety learning for integrated care boards**

**Safety learning for integrated care boards ICB/2026/024:**

HSSIB suggests that integrated care boards, through implementation plans for modern diabetes technology – including hybrid closed loop systems and continuous glucose monitors – proactively seek to reduce inequitable availability for their local populations who would safely benefit from these technologies.

## 2.2 Design of insulin pen devices

2.2.1 HSSIB's investigations also identified incidents where the design of insulin-based technologies and devices had contributed to patient harm. Examples included harm from an HCL system (see report 3, section 2.2); missed (see report 3, section 2.1) or incorrect (see report 2, section 2.1) doses of insulin via pen devices; and deliberate self-harm (see report 1, section 2.1).

2.2.2 This section focuses on insulin pen devices. It draws on evidence including incidents where device design had enabled the administration of large volumes of insulin, incorrect selection of device or dose, and missed doses of insulin. Similar incidents have been identified internationally (Institute for Safe Medication Practices, 2017).

2.2.3 The investigation observed patients using insulin pen devices and heard about their experiences. Design factors that contributed to incidents included:

- **Presentation of information:** wording and numbers did not support selection of the correct device and dose, particularly for people with visual impairment and/or limited literacy. The size of information, colour schemes, colour contrast and fonts influenced whether information could be read. Similar insulin names created the potential for incidents where confusion was created by the similar looking and sounding names.
- **Feedback of information:** devices did not make it clear to the person that the full dose had been administered. In some cases, people found it difficult to apply the amount of force needed to make the device work, particularly those with dexterity issues. Devices did not always support people to remember whether, or when, they had already administered a dose.
- **Safety functionality:** devices did not always prevent intended or unintended misuse, such as dialling up too high a dose or missing necessary steps, including priming the device. Report 1 (section 4.2.15) found no reliable design option for someone who needs insulin but is at risk of self-harm.

2.2.4 These incidents demonstrated how the design of some insulin pen devices was not sufficiently user centred. The devices did not always support users with disabilities and impairments to administer insulin safely. User-centred design is a process that seeks to understand the users of a product, their needs, the tasks they need to complete, and the environments in which those tasks are performed. It is a fundamental component of the initial design of a product and its ongoing development throughout the product life cycle.

2.2.5 A lack of user-centred design for insulin pen devices has been described by researchers, with evidence showing that devices do not consider the full range of users, their needs, and the contexts in which they use devices (Heron et al, 2013; Rini et al, 2019). The investigation also heard from diabetes specialists that devices appeared to be designed with a theoretical “standard person” in mind – that is, a person who can see and read the words and numbers on a pen device, remember all the steps required for insulin administration, and physically complete the task. In reality, every person is different, and it was the perception among specialists that manufacturers had given limited consideration to the diversity of the population.

**Manufacturers and user-centred design**

2.2.6 The investigation met with the Medicines and Healthcare products Regulatory Agency (MHRA) to understand its role in oversight of insulin devices. MHRA told the investigation that there are different types of insulin pen device:

- reusable – require the user to insert an insulin cartridge. These are considered medical devices and regulated under the UK Medical Devices Regulation (2002)
- pre-filled – combined medication and device. These are considered a medicine and regulated under the Human Medicines Regulations 2012. The device component must meet essential requirements under the Medical Devices Regulation (2002) with regard to safe use.

2.2.7 The Medical Devices Regulations (2002) set requirements for devices and manufacturers, including that:

- Devices must conform with essential requirements set out in the Regulations. They must be safe when used by intended users. The Regulations refer to the need for users to be identified and for risks arising from differences in their needs to be recognised; they do not refer to a standard user.
- As set out in a 2024 amendment to the Regulations, manufacturers must operate a post-market surveillance (PMS) system capable of collecting real-world safety and performance data, detecting trends and risks, and identifying corrective or preventive actions.

2.2.8 The MHRA (2021) has published guidance on human factors and usability engineering for medical devices. Medical devices can demonstrate conformity with the essential requirements in the Regulations for user-centred design by complying with designated standards. The MHRA highlights standard IEC 62366-1:2015, which specifies a process for manufacturers to analyse, develop and evaluate the usability of a medical device as it relates to safety (International Organization for Standardization, 2015). Conformity is assessed and approved by Notified Bodies (designated by EU Member States and support CE marking) and Approved Bodies (designated by the MHRA and support UKCA marking). Medical devices using CE and/or UKCA marking are allowed on the UK market.

2.2.9 The investigation engaged with manufacturers of insulin pen devices to understand how they ensure user-centred design is included in the development of their devices. Manufacturers described the application of user-centred design principles to the initial and ongoing development of devices, how they ensured conformity with regulations for the UK market, and evolved insulin pen design for several decades in response to clinical practice and user needs. Examples of improvements made to devices through PMS were shared. These included improvements to support ease of use and readability of dose numbers; redesign of pen shape to support someone with a weakened grip to hold and use the device; colour-coded pens for different insulin types; and louder audible clicks to confirm insulin delivery.

2.2.10 Manufacturers confirmed that their focus was on supporting patient safety in line with the intended use scenarios for insulin pen devices, for example by minimising the unintentional administration of incorrect insulin doses. As described in report 1 (section 4.2), where devices were used outside their intended purpose – such as to intentionally administer too much or too little insulin – this was not considered by manufacturers to indicate a design issue and therefore technical changes were not sought. However, the investigation heard challenge from the families of patients who had died through the use of insulin pen devices to self-harm, that if a device can be misused because of a disability, then this is a design issue.

2.2.11 The investigation explored the gap between manufacturers' assurances of user-centred design and healthcare staff perceptions. Industry and innovation stakeholders said that, despite design developments, people with disabilities and impairments – including learning disabilities, mental health needs and reduced dexterity – continued to experience recurring issues. They emphasised the importance of reporting issues through PMS, either via the MHRA's Yellow Card scheme or directly to manufacturers, but said these mechanisms were underused, limiting feedback. Reliance on individuals to report issues was identified as a gap in the safety management system for medical devices. Stakeholders further highlighted constraints relating to technological feasibility and economic viability (see Sparre et al, 2023).

**HSSIB makes the following safety observation**

**Safety observation O/2026/095:**

Organisations and individuals can improve patient safety by ensuring misuse – including deliberate self-harm – and abnormal use of diabetes technologies and insulin pen devices are reported to the Medicines and Healthcare products Regulatory Agency via their Yellow Card reporting site.

2.2.12 The investigation noted that intelligence about how insulin pen devices had contributed to harm was held in multiple locations. The national Learn From Patient Safety Events (LFPSE) service contains multiple reports of incidents involving insulin pen devices. For example, a search of LFPSE using the keywords 'insulin' and filter 'devices' identified over 100 incidents in December 2025, including misuse, abnormal use and device malfunctions. Manufacturers may not be aware of the scale of the potential risk because relevant data is held elsewhere.

**Summary and learning**

2.2.13 The investigation found that the design of insulin pen devices did not always 'fit the user' and this had contributed to patient harm. Design had enabled patients with a range of disabilities to unintentionally and intentionally miss doses or administer incorrect doses of

insulin. While manufacturers incorporate user-centred design principles into device development, the investigation found evidence to suggest that the disabilities considered in this series of investigations – notably people with learning disabilities and those with mental health needs – were not clearly considered or designed for. People with certain disabilities are known to be systematically excluded from medical research, device design and clinical evaluation (for example, Camanni et al, 2023).

2.2.14 The Medical Devices Regulations (2002) require manufacturers to design devices that are safe and effective. The Regulations reference the need to 'estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse'. The families of those who have lost loved ones through self-harm with insulin where a mental health problem was also a factor challenged that this was "foreseeable misuse", but the investigation did not identify evidence that the risk had been estimated or evaluated. The investigation also noted that, while the Regulations require manufacturers to consider intended users, it does not explicitly require consideration of protected characteristics.

2.2.15 The investigation faced challenges identifying how best to influence insulin pen device design for patient safety, most notably because design and development is often undertaken by multinational pharmaceutical companies with world-wide supply of products. The investigation approached the MHRA to understand how a safety recommendation could be developed to help influence improved user-centred design of insulin pen devices for the UK market. The MHRA clarified that they are not part of the design process for medical devices, rather designs are approved by Notified and Approved Bodies through conformity assessments. The MHRA has direct oversight of UK Approved Bodies, but no authority over EU Notified Bodies (see 2.2.8). Therefore both a recommendation and observation have been made.

**HSSIB makes the following safety recommendation**

**Safety recommendation R/2026/100:**

HSSIB recommends that the Medicines and Healthcare products Regulatory Agency – through their oversight of Approved Bodies – ensures conformity assessments promote comprehensive assessment of insulin-related medical devices that:

- consider the needs, characteristics and capabilities of diverse user populations, including people with protected characteristics, and the potential impact of device design on equitable access, usability and safety for the intended user
- identify, assess and mitigate risks associated with intentional and unintentional misuse, including situations where a person's physical, cognitive or mental health needs may affect the safe use of a device.

This is to support the safety of the diverse range of people who administer insulin, and to promote the development of devices that better recognise and mitigate risks associated with insulin administration.

**HSSIB makes the following safety observation**

**Safety observation O/2026/096:**

Approved and Notified Bodies can improve patient safety by ensuring that insulin-related medical devices meet the needs, characteristics and capabilities of diverse user populations, including situations where a person's physical, cognitive or mental health needs may affect the safe use of a device. Design should also consider how to reduce misuse of insulin pen devices and the potential for deliberate self-harm.

2.2.16 While developing its safety recommendation, the investigation noted a recommendation made in a report by the Patient Safety Commissioner (2025) for exploration of the accessibility of medical devices for people with sensory impairment. Diabetes UK confirmed that they were working with NHS England to explore the lived experience of people with sensory impairment and their use of diabetes technology including through workshops, with outputs of this work expected later this year.

2.2.17 The investigation further engaged with the Association of British HealthTech Industries (ABHI) and the Association of the British Pharmaceutical Industry (ABPI) to understand their roles in influencing design. These bodies are positioned to support collaboration between the NHS and industry, and they recognised the issues being raised by the investigation around insulin pen design. ABHI and ABPI supported the idea of future collaborative work between the NHS and industry to explore design for safety.

**HSSIB makes the following safety recommendation**

**Safety recommendation R/2026/101:**

HSSIB recommends that the Association of British HealthTech Industries and the Association of the British Pharmaceutical Industry facilitate the engagement of manufacturers with healthcare and people with lived experience to inform inclusive and

user-centred design of insulin pen devices based on the findings of this investigation. This is to ensure that insulin pen devices meet the diverse needs of users and address risks associated with the task of insulin administration.

2.2.18 The investigation heard about specific insulin pen devices that may be more accessible for some people with particular needs, including smart pens (see 1.2.2). Diabetes UK (2025c) has described positive outcomes for patients using smart pens and stated that their use 'bridges' a gap between injections and pumps. Manufacturers have also published information about the accessibility of their pen devices and NHS England (2023) has published a technology decision-support tool for people with type 1 diabetes. However, the investigation also identified limited understanding across the workforce about the best fit between patient and device. This was attributed to the large number of different devices available and limited supporting guidance.

**HSSIB makes the following safety observation**

**Safety observation O/2026/097:**

National organisations with responsibilities for supporting the care of people with diabetes – in collaboration with pharmaceutical companies – can improve patient safety by providing evidence-based guidance to the healthcare system on the design of different insulin pen devices and the patient needs – such as dexterity or cognitive – they are best suited for.

2.2.19 HSSIB investigations include local-level learning where this may help providers/ organisations respond to a patient safety issue at the local level. Informed by the findings in this section, the investigation shares the following local-level learning for organisations that provide care to people with diabetes who use diabetes technology.

**Local-level learning**

- How does your organisation ensure staff who are likely to be caring for patients who use diabetes technology have the required knowledge and skills to support patients to manage their technology safely?
- How does your organisation support staff to explore how a patient's disability or impairment may influence their ability to use an insulin pen device or diabetes technologies?

- Does your organisation have resources to support prescribers to know which insulin pen devices are suited to patients with different disabilities or impairments?
- How does your organisation ensure staff are aware of their responsibilities to report incidents associated with diabetes medication, devices and technology, including to manufacturers and the Medicines and Healthcare products Regulatory Agency?

# 3. Analysis and findings – community diabetes care

This section describes the investigation's analysis and findings in relation to the wider issues identified across HSSIB's series of reports. These cross-cutting themes relate to the provision of specialist and collaborative support to patients with diabetes (requiring insulin) in community settings.

## 3.1 Cross-cutting themes

**Meeting patient needs**

3.1.1 The reports described how patient circumstances can make them more vulnerable to harm from insulin, but that those circumstances may not be recognised. Examples included where a disability or impairment could affect a person's ability to physically administer their insulin or to make decisions about their diabetes care.

3.1.2 Fluctuating mental capacity to make decisions about self-management of diabetes and insulin was repeatedly seen to contribute to patient harm where safety plans had not been made for when a person may lose capacity (see report 1 section 4.1; report 2, section 3.3; report 3, section 3.1). Staff described limited support for the assessment, review and recording of concerns about a patient's capacity to make decisions about their self-management. These findings contributed to safety observation (O/2026/085) in report 2.

3.1.3 The reports further described factors that made it difficult for healthcare staff to meet the varying needs of patients. These included limited resources, problems with how services were designed, and access to support and information. Also, staff had not always been equipped with the skills to engage effectively with patients. In report 1, section 3.1, for example, diabetes specialist care was not always trauma-informed, which led to patients disengaging from services.

**Access to support for services and staff**

3.1.4 The reports described barriers to services seeking advice, clinical information and support from each other and the influence this had on collaborative care planning. Limited collaboration was seen between various services including general practice, community nursing, diabetes specialist, mental health and learning disability services. In particular, staff found it difficult to access advice when making Mental Capacity Act (2005) assessments and when considering confidential information sharing (see report 1 section 4.1).

3.1.5 The reports further described how the digital infrastructure and poor interoperability between IT systems used by different services limited clinical information sharing. This affected staff decision making and therefore created risks to patient safety. Disconnected digital systems and limited interoperability are well-recognised risks to patient safety and ones that HSSIB continues to investigate (Health Services Safety Investigations Body, 2025c; 2026c).

3.1.6 The issue of access to support also included equipping non-diabetes-specialist staff with the knowledge to manage diabetes and insulin safely and knowing when specialist support was required. Concerns around workforce knowledge were also found by HSSIB's (2026b) investigation into diabetes care in inpatient settings. That investigation found that gaps in diabetes education 'is one of the systemic challenges that contributes to the ongoing risks and harms for one of the largest, and growing, cohorts of [patients]'. Getting It Right First Time (GIRFT) (2020) has also recommended that, for inpatient care, training and competency assessment should be in place for healthcare professionals who care for patients who need insulin.

**Discrimination and access to care**

3.1.7 The reports described disparities in access to care and support for patients with diabetes (requiring insulin), and the impact this had on patient safety. For patients with disabilities or impairments, such disparities were affected by the ability of services to identify and meet patient needs, but also by assumptions about what patients could or could not do. Deeply engrained prejudices, for example about people with learning disabilities, influence healthcare delivery and continue to persist (for example, Ramsey et al, 2022).

3.1.8 The investigations found evidence to suggest that some people may have been discriminated against when accessing diabetes care, including diabetes technology (as described in 2.1). Specific examples were where people had been treated unfairly because of age (see report 2, section 2.2), a learning disability (see report 3, section 3.1) or a mental health problem (see report 1, section 4.2). Further inequalities were described in relation to factors such as socioeconomic status, geography, and housing status.

3.1.9 In England, the public sector equality duty is a legal requirement for organisations carrying out public functions. It requires organisations to have due regard to the need to end discrimination, and to advance equal opportunities between people who have a protected

characteristic and those who do not. In support, the Equality and Human Rights Commission (2024) provides guidance on considering equality in policy making. The findings of this series of investigation suggests that best practice in relation to equality is not always being followed.

## 3.2 Community-focused strategy

3.2.1 The cross-cutting themes above are factors that impair the delivery of safe, equitable and effective diabetes care in community settings. They highlight the need for collaboration – between community, general practice, mental health, learning disability and diabetes specialist services – and preparation of the workforce to deliver care, particularly in light of increasing technological complexity. These themes also exist within a context of increasing demand – described in section 2.1.23 as an "avalanche" – and variation in diabetes specialist provision across the country (considered in report 1, section 3.1).

3.2.2 National stakeholders described no clear and cohesive strategy to address the above factors, and that there had been limited community-focused safety improvement work to date. Getting It Right First Time (GIRFT) (2020) has undertaken nationally commissioned work on inpatient care, which included a focus on insulin safety, but told the investigation of limited resource to extend this for community settings. NHS England confirmed that, because already limited resource was focused on the roll-out of hybrid closed loop (HCL) systems, commissioning community work through GIRFT was not possible.

3.2.3 The investigation was unable to identify specific plans, programmes or strategies to address the factors influencing patient safety for patients with diabetes (requiring insulin) in community settings; the exception was work launched by NHS England in response to the safety recommendations for report 2 in this series. National stakeholders did share that the development of plans for neighbourhood health (NHS England, 2025) offered opportunities to consider how diabetes care in the community could be better provided in the future. Neighbourhood health 'puts the person at the centre of how we deliver their health and care by organising services so they can work together to serve a defined population' (Department of Health and Social Care, 2026) and Diabetes UK (2025d) has published recommendations for diabetes care in neighbourhood health.

3.2.4 National stakeholders told the investigation that diabetes care was on the agenda for neighbourhood health, but that further details about "what this looks like" were unclear. Concerns were described that, without clarification of the aims and objectives, shared-care agreements and clear funding arrangements, plans would falter.

3.2.5 HSSIB's (2026b) investigation on diabetes care in inpatient settings made a safety recommendation for NHS England/Department of Health and Social Care to set out the expectations and responsibilities of different parts of the healthcare system in relation to

inpatient diabetes care. This was in light of the growing incidence of diabetes in England that is ‘set to be one of the major clinical challenges of the 21st century’ (NHS England, n.d.a). This investigation has identified a similar need for community-based diabetes care, bringing together different parts of the healthcare system around the patient to address the cross-cutting themes identified in this series (see 3.1).

**HSSIB makes the following safety recommendation**

**Safety recommendation R/2026/102:**

HSSIB recommends that NHS England/Department of Health and Social Care, working with integrated care boards, develops specifications for community and home-based diabetes care to address gaps in collaboration between provider organisations that impact on the safety of patients. This should include consideration of the:

- availability of, and access to, specialist diabetes services in community settings
- shared care arrangements between specialist diabetes, mental health (including specialist eating disorder), learning disability, and general practice services
- capability and capacity of services to care for the increasing number of people with diabetes and the use of diabetes technologies
- identification of, and ways to address, disparities in access to care, and removal of disadvantages experienced by people with protected characteristics.

This is to support a co-ordinated approach to diabetes care, such as through Neighbourhood Health plans, to enable services to safely and effectively care for people with diverse cognitive, physical, sensory and mental health needs.

## 3.3 Workforce capability

3.3.1 A repeated issue heard to influence patient safety was gaps in the knowledge of non-specialist community staff when supporting patients with diabetes, including those requiring insulin. Inconsistencies in diabetes and insulin awareness training were described at undergraduate and postgraduate levels. These inconsistencies were heard to result from the absence of a nationally mandated minimum standard for diabetes care or insulin safety education, and from capacity challenges among diabetes specialist teams to provide education. In contrast, competencies do exist for diabetes specialist nursing but are not considered universal (for example, Trend Diabetes, 2024).

3.3.2 Concerns around workforce capability were also identified by HSSIB's (2026b) investigation focusing on insulin administration in inpatient settings. That investigation heard from staff that education was often too technical and did not equip them with the basic rules or core principles needed when supporting patients with diabetes requiring insulin, including those who used CGMs and HCL systems. That report also highlighted the crucial role of diabetes specialist teams in education, as well as their limited capacity.

3.3.3 HSSIB explored whether a safety recommendation could be made to influence a national education programme for diabetes management and insulin safety. However, there is no single body to which a recommendation could be directed, because responsibility for training is spread across educational institutions, NHS England, professional bodies and individual organisations. This investigation therefore echoes the safety observation made by HSSIB's (2026b) investigation focused on inpatient settings while building on the observation made in report 1 for the care of patients who also have a mental health problem.

**HSSIB makes the following safety observation**

**Safety observation O/2026/098:**

Organisations involved in the provision of clinical undergraduate and postgraduate education programmes, and trust preceptorship/induction programmes, can improve patient safety by using the findings of HSSIB's investigations to prioritise diabetes care and insulin management education and training as appropriate, with coverage including the risks that the use and misuse of insulin can present for patients with a mental health problem.

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## 5. Appendix 1 – previous reports in this series

This section reviews the safety recommendations of the previous reports in this series and summarises responses at the time of publication of this final report. Specific findings and associated learning can be found via the provided links.

## Report 1 – published February 2026

The report and its findings are available at: Insulin: supporting safe self-administration for patients in the community with a mental health problem.

The report made three safety recommendations and two safety observations, suggested two areas of safety learning for integrated care boards (ICBs), and set out local-level learning for mental health and specialist diabetes services.

**Safety recommendation R/2026/073:**

HSSIB recommends that NHS England/Department of Health and Social Care develops a strategy for improving collaboration between mental health teams and specialist diabetes services, that includes consideration of responsibilities for integrated working at national, regional and local levels. This is to support future integration of services that will benefit all patients with mental health and diabetes care needs, including patients who are required to self-administer insulin and patients with type 1 diabetes and disordered eating.

The safety recommendation in this final report builds on the recommendation above. NHS England has confirmed that it will provide a joint formal response to the related recommendations made across the investigation series.

**Safety recommendation R/2026/074:**

HSSIB recommends that the National Institute for Health and Care Research, in collaboration with relevant research and policy stakeholders: 1) maps the knowledge gaps surrounding type 1 diabetes and disordered eating (including those identified in this investigation); and 2) assesses the priority and feasibility of commissioning research to help address those gaps. This is to help develop new knowledge to inform future decisions for the delivery of safe and effective care for this group of patients.

At the time of publication of this final report, HSSIB is engaging with the National Institute of Health and Care Research and the Medical Research Council to confirm the response and actions to this recommendation.

**Safety recommendation R/2026/075:**

HSSIB recommends that Royal College of Psychiatrists, through collaboration with relevant stakeholders, develops a strategy that: 1) supports consistent recognition of patients with type 1 diabetes and evidence of disordered eating; and 2) identifies associated care responsibilities for providers of mental and physical health services. This is to help improve the NHS's recognition of patients who are affected and to support decisions around the commissioning of services.

The Royal College of Psychiatrists are supportive of this recommendation but confirmed that they currently did not have the capacity to undertake the work involved. The College will further consider the recommendation should opportunity become available.

## Report 2 – published May 2026

The report and its findings are available at: Insulin: supporting safe self-administration for patients in the community with a disability.

The report made two safety recommendations and one safety observation, suggested two areas of safety learning for integrated care boards (ICBs), and set out local-level learning for organisations supporting the self-administration of insulin in community settings.

**Safety recommendation R/2026/084:**

HSSIB recommends that NHS England/Department of Health and Social Care provides guidance to integrated care boards and community providers setting out expectations for service models that empower and support people to manage and administer insulin in community settings. This is to support recognition of models that have safely, effectively and equitably engaged patients, their families and carers, including through the use of modern diabetes technology for self-management.

In response to this recommendation and R/2026/085 below, NHS England have confirmed that they will develop a task and finish group to oversee delivery. The output will be a tool for use in community settings which will be incorporated into guidance and tested.

**Safety recommendation R/2026/085:**

HSSIB recommends that NHS England/Department of Health and Social Care develops a tool for use in community settings to support the assessment of competency of patients, their families and carers to manage and administer insulin and care for people

with diabetes. This should include recognition of a person's circumstances, the impact of disabilities and impairments, and potential adjustments to support administration where safe to do so. This is to support consistency in how competency is assessed for the safe management of insulin within the context of modern diabetes care.

See R/2026/084 for the response to this recommendation.

### Report 3 – published August 2026

The report and its findings are available at: Insulin: supporting safe self-administration for patients in the community with a learning disability.

The report made one safety recommendation and set out local-level learning for organisations supporting people with a learning disability to manage their diabetes and insulin.

**Safety recommendation R/2026/094:**

HSSIB recommends that the National Institute for Health and Care Research, in collaboration with relevant research and policy stakeholders, assesses the feasibility of research, and supports its commissioning, to address the gaps in knowledge around services, device and technology requirements for support of people with a learning disability to self-administer insulin for diabetes. This should be undertaken through co development with people with a learning disability and aim to create new knowledge to inform delivery of safe and effective care for this group of patients.

At the time of publication of this final report, HSSIB is awaiting a response from the National Institute of Health and Care Research.

## 6. Appendix 2 – investigation approach

### Terms of reference

The investigation examined the following questions relating to the safety of people who self-administer insulin, through engagement with patients, families, staff and organisations/providers of primary, community and secondary care:

- What are the core processes involved in care for patients who self-administer insulin in community settings?

- How do patients access support for their insulin in relation to administration, monitoring and in the long term?
- What other intersectional factors influence the care of patients?

## Evidence gathering

The investigation engaged with and/or visited the organisations/providers described across the reports in this series. Further evidence was gathered from policy and academic literature, the Strategic Executive Information System and the Learn From Patient Safety Events system (national databases that capture information about patient safety incidents), and reviews of coroners' reports to prevent future deaths.

### Analysis of findings

Findings were identified following triangulation of evidence and consultation. Various analysis approaches were used throughout the series including the Systems Engineering Initiative for Patient Safety (Holden et al, 2013). Specifically for this report, a standard thematic analysis approach was used.

### Stakeholder engagement and consultation

The investigation engaged with the stakeholders listed below, who contributed evidence to the investigation. Stakeholders also contributed to the development of the safety recommendations.

- Association of British Clinical Diabetologists
- Association of British HealthTech Industries
- Association of the British Pharmaceutical Industry
- Breakthrough T1D
- Care Quality Commission
- Community Pharmacy England
- Department of Health and Social Care
- Diabetes Specialist Nurse Forum UK
- Diabetes UK
- Equality and Human Rights Commission
- Getting It Right First Time
- Health Innovation Network
- Medicines and Healthcare products Regulatory Agency
- NHS England

- Primary Care Diabetes and Obesity Society
- manufacturers of insulin pen devices
- other experts including academics in diabetes.

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