NICE advice

t:slim X2 insulin pump for managing blood glucose levels in type 1 diabetes

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is the t:slim X2 insulin pump. It is used for managing blood glucose levels in type 1 diabetes.
- The **innovative aspects** are using advanced algorithms with a continuous glucose monitor to predict low glucose and suspend insulin delivery. The technology software, Control-IQ, can also adjust basal insulin and give correction doses.
- The intended **place in therapy** would be as an alternative to other sensor-augmented insulin pumps for people with type 1 diabetes.

- The **main points from the evidence** summarised in this briefing are from 6 studies (including 4 randomised controlled trials, 1 randomised crossover study and 1 retrospective study). They included a total of 6,622 patients in a home setting. The studies show that the t:slim X2 insulin pump, with predictive low-glucose suspend technology or advanced hybrid closed-loop system, is more effective than comparators.
- **Key uncertainties** around the evidence or technology are that the studies were done in the US. This means generalisability to the NHS may be limited.
- **Safety issues** identified are a Medicines and Healthcare products Regulatory Agency Medical Device Alert for faulty mains power adaptors. The users of the affected pumps were identified, and adaptors replaced.
- The **cost** of t:slim X2 insulin pump is £3,150 to £3,350 per unit with a cost of £1,588 per year for consumables (excluding VAT).

The technology

The t:slim X2 insulin pump (Tandem Diabetes Care) is for continuous subcutaneous insulin delivery to manage blood glucose levels in people with type 1 diabetes. The device is up to 38% smaller than other insulin pumps and has a watertight aluminium case and shatter-resistant colour touch screen interface. The flat insulin cartridge accommodates up to 300 units of insulin. Rapid-acting insulin is delivered from the device through thin flexible tubing to a cannula placed under the skin. The infusion site is changed every 2 days to 3 days. The t:slim X2 pump can be altered to give different rates of basal insulin. It also has an integrated bolus calculator that can record carbohydrates, to help with bolus delivery. The device allows 6 profiles to be created for basal insulin delivery depending on the needs of the user.

The t:slim X2 insulin pump can be used as a standalone pump or can integrate with a G6 continuous glucose monitor (CGM; Dexcom). This briefing focuses on the t:slim X2 pump with CGM. The G6 CGM can provide real time glucose measurements by bluetooth from a CGM transmitter. When the pump is used with the G6 CGM additional features, Basal-IQ or Control-IQ algorithms are available. Basal-IQ uses values from the G6 CGM to reduce the frequency and duration of low-glucose events by predicting glucose levels 30 minutes in advance. It can suspend insulin if levels are expected to drop below 4.4 mmol per litre, or if an actual CGM reading is 3.9 mmol per litre or less. Basal-IQ software is currently being optionally upgraded to Control-IQ (if existing users want to

upgrade and if healthcare professionals think it is clinically appropriate). This is an advanced hybrid closed-loop system. Control-IQ can adjust basal insulin when glucose levels are predicted to go above 8.9 mmol per litre and give a correction bolus if glucose levels are predicted to go above 10.0 mmol per litre. It can also adjust basal insulin if glucose levels are predicted to go below 6.25 mmol per litre and suspend delivery if the predicted value is below 3.9 mmol per litre. Control-IQ also uses activity and sleep settings.

The device has a rechargeable battery, USB ports and the software can be updated remotely using a personal computer during the 4-year warranty of the pump. Patients can also upload their device data using the Diasend (Glooko) or Tidepool (Tidepool Project) diabetes data management systems. Then their doctor or nurse can review patterns in data and help make changes in pump settings when necessary.

Innovations

The technology combines glucose monitoring using a CGM with advanced algorithms in the insulin pump to predict low glucose and suspend insulin delivery. The Control-IQ algorithm software can adjust basal insulin levels and give correction doses. The company claims that these systems reduce the effect of hypoglycaemic events and ensure patients are within optimal glucose range more of the time. Using a Dexcom G6 CGM also removes the need for sensor calibration, which uses finger prick testing. The t:slim X2 insulin pump is the only pump currently available in which software can be remotely updated.

Current care pathway

Continuous subcutaneous insulin infusion (insulin pump) therapy is recommended as a treatment option for adults and children 12 years and older with type 1 diabetes if:

- attempts to meet target haemoglobin A1c (HbA1c) levels with multiple daily injections result in the person experiencing disabling hypoglycaemia **or**
- HbA1c levels have remained high (8.5% [69 mmol/mol] or above) with multiple daily injections, despite a high level of care.

Continuous subcutaneous insulin infusion therapy is recommended as a treatment option for children younger than 12 years with type 1 diabetes if multiple daily injections therapy is considered impractical or inappropriate. Children with insulin pumps would be expected

to have a trial of multiple daily injections between 12 years old and 18 years old.

Continuous glucose monitoring for adults with type 1 diabetes is recommended for those who have any of the following despite optimised use of insulin therapy and conventional blood glucose monitoring:

- more than 1 episode a year of severe hypoglycaemia with no obvious preventable cause
- complete loss of hypoglycaemia awareness
- more than 2 episodes a week of asymptomatic hypoglycaemia
- extreme fear of hypoglycaemia
- hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day.

Children and young people should be offered real-time continuous glucose monitoring with alarms if they have frequent severe hypoglycaemia, impaired awareness of hypoglycaemia, or cannot recognise or communicate symptoms of hypoglycaemia.

The following guidance has been identified as relevant to this care pathway:

- NICE's guideline on type 1 diabetes in adults: diagnosis and management
- NICE's guideline on diabetes (type 1 and type 2) in children and young people: diagnosis and management
- NICE's diagnostic guidance on integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes (the MiniMed Paradigm Veo system and the Vibe and G4 PLATINUM CGM system)
- NICE's technology appraisal guidance on continuous subcutaneous insulin infusion for the treatment of diabetes mellitus.

Population, setting and intended user

The t:slim X2 insulin pump is for patients with type 1 diabetes when it is appropriate to use insulin pump therapy instead of multiple daily injections. This device would be used in a

home setting. The pump is not for use in children under 6 years old. There is no evidence for using the technology in pregnant women, people on dialysis, or people who are critically ill. Users with cognitive, visual and physical impairments may need a care partner to be co-trained in pump therapy to recognise pump functions, including alerts. The company provides training for healthcare professionals as well as patients when they start using the pump. The company also provides ongoing technical support with a 24-hour, 7 days a week freephone service.

Costs

Technology costs

The company has provided prices for the t:slim X2 insulin pump with associated consumables as well as the cost of the Dexcom G6 CGM. The company states that the insulin pump and consumables will cost a total of £9,501 to £9,701 over a 4-year period (the duration of the device warranty) or £20,081 to £20,281 with full time use of the CGM (over 4 years, with consumables).

Breakdown of individual devices and consumables:

- t:slim X2 insulin pump (with 4 year warranty) costs £3,150 with Basal-IQ or £3,350 if purchased for use with the Control-IQ algorithm.
- Insulin cartridges (10-pack box) cost £32.25.
- Infusion sets (10-pack box) cost £89.90.
- It is estimated that a patient would use around 13 boxes of cartridges and infusion sets each year, totalling £1,588 per year on consumables. This number may be higher if there are any problems with the cartridge or infusion set leading to earlier replacement of consumables.
- Dexcom G6 CGM: £2,645 per year. This estimate is based on 4 transmitters (£200 each; changed every 3 months) and 36 sensors (£153.75 for a pack of 3; each sensor lasting 10 days).
- Discounts may be available depending on the volume purchased.

Costs of standard care

Alternative insulin pumps that have compatible CGMs listed are MiniMed 670G (Medtronic), MiniMed 640G (Medtronic), MiniMed 780G (Medtronic) and A6 system (Medtrum). The company states that the MiniMed 670G or 780G with a Guardian Sensor 3 CGM (Medtronic) would be the most comparable system.

The MiniMed 670G insulin pump with CGM starter kit (which includes a Guardian Link 3 transmitter and 5 Guardian Sensor 3s) costs £3,730 (excluding VAT). Guardian Sensor 3 costs £525 for a pack of 10. Each sensor lasts 7 days, leading to a cost of around £2,730 per year.

The MiniMed 640G insulin pump costs £2,995 and the transmitter and charger costs £490 (all excluding VAT). Consumables including glucose sensors, infusion sets and insulin reservoirs cost around £4,800 (excluding VAT) per year. Over 4 years this would cost £22,685.

Resource consequences

The company states that this pump is currently used in over 130 NHS clinics, with over 1,900 patients using the device in the UK. The device could be an alternative to other insulin pumps provided by the NHS. Patients may want to use a compatible CGM for full use of the device functions, such as Basal-IQ or Control-IQ. The company also states this device could be used by patients who already have a G6 CGM.

Regulatory information

The t:slim X2 Insulin Pump is CE marked as a class IIb medical device. It received its CE mark in 2018.

The following manufacturer field safety notices or medical device alerts for this technology have been identified:

- A Medicines and Healthcare products Regulatory Agency Medical Device Alert for t:slim X2 insulin pump. This alert was for faulty mains (A/C) power adaptors. The users of the affected pumps were identified, and adaptors were replaced.

- Further safety concerns have been identified through the Manufacturer and User Facility Device Experience database. These include pumps turning off and becoming unresponsive or failing to charge, tubing failing to fill with insulin, a person having too much insulin delivered, and insulin and battery gauges being reported as inaccurate.
- Brown et al. (2019) noted that the use of the Control-IQ software was temporarily suspended during the study (in March 2019). This was because of a software error leading to insulin delivery stopping for several hours, or an incorrect bolus being given when insulin delivery restarted. However, this did not lead to any serious adverse events and was rectified. This study also reported 1 instance of diabetic ketoacidosis and 12 instances of hyperglycaemia or ketosis without diabetic ketoacidosis in the group using the t:slim X2 insulin pump.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

The technology is intended to benefit people with type 1 diabetes. People who may not be able to manage their blood glucose using multiple daily insulin injections because of age, learning difficulties or other disabilities may also benefit from this device. There is no evidence for using the technology in pregnant women, people on dialysis and people who are critically ill. Users or their care partner must also have adequate vision or hearing to recognise device alerts. Age, disability, sex and pregnancy are protected characteristics under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with NICE's interim process and methods statement for the production of medtech innovation briefings. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

There are 6 studies summarised in this briefing, including 4 randomised controlled trials, 1 randomised cross over study and 1 retrospective study. In total, there were 6,622 people included in these studies.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The studies included have appropriate sample sizes and present relevant outcome measures. Some of the studies evaluate long-term outcomes, but 2 studies are limited by a short study period. Using multiple insulin pumps as comparators could make comparisons with the device more difficult. All studies were done in the US and so the evidence may not generalisable to the NHS.

Brown et al. (2019)

Study size, design and location

Multicentre randomised controlled trial over 6 months in 168 people with type 1 diabetes in the US.

Intervention and comparator(s)

Intervention: closed-loop system comprised of a t:slim X2 insulin pump with Control-IQ and a Dexcom G6 continuous glucose monitor (CGM).

Comparator: sensor-augmented pump (t:slim X2 insulin pump without Control-IQ in patients new to insulin pump use) and a CGM.

Key outcomes

The percentage of time glucose levels were within the target range increased from 61% (plus or minus 17%) at baseline to 71% (plus or minus 12%) in the closed-loop group but remained unchanged in the control group (59%, plus or minus 14%). There were lower

glycated haemoglobin levels at 26 weeks in the closed-loop group than the control group (mean difference -0.33%; 95% confidence interval [CI], -0.53 to -0.13; p=0.001). There were 17 adverse events reported (including 1 instance of diabetic ketoacidosis) in the closed-loop group compared with 2 in the control group (p=0.05).

Strengths and limitations

The study randomised people in a 2:1 ratio to the closed-loop and control group, respectively. Both groups had similar patient demographics and baseline blood glucose control. No exclusions were made based on glycated haemoglobin level. There were also 100% of people who stayed in the study for the whole duration, and a high level of adherence to the assigned devices in both groups.

Brown et al. (2020)

Study size, design and location

Randomised controlled multicentre trial of 109 people with type 1 diabetes (aged 14 to 72) over 3 months in the US. This is an extension study to Brown et al. (2019).

Intervention and comparator(s)

Intervention: closed-loop system comprised of a t:slim X2 insulin pump with Control-IQ and a Dexcom G6 CGM.

Comparator: predictive low-glucose suspend system comprised of a sensor-augmented pump and a CGM.

Key outcomes

People who continued to use the closed-loop system from the first trial could maintain time in range (70 to 180 mg/dl) for this 3-month extension period (71.1% plus or minus 11.2% at baseline and 67.6% plus or minus 12.6% after the extension period; baseline measurements calculated as the last 13 weeks of the initial trial). This is compared with the control group, which went from 70.0% plus or minus 13.6% at baseline to 60.4% plus or minus 17.1% at the end of the extension period. HbA1c at the end of this study was lower in the intervention than the control group (7.2% compared with 7.5%; p=0.0035).

Strengths and limitations

There was no remote monitoring and only 1 clinic visit in this study to reflect real-world device usage. Because this was an extension study, the device users were more familiar with the technology potentially leading to better glucose control. Control-IQ was suspended for 4 weeks during this study.

Forlenza et al. (2019)

Study size, design and location

Multicentre randomised controlled trial in 24 school-aged children (6 years to 12 years) with type 1 diabetes in the US.

Intervention and comparator(s)

Intervention: closed-loop system comprised of a t:slim X2 insulin pump with Control-IQ and a Dexcom G6 CGM as well as a Dexcom G5 CGM (because remote monitoring for Dexcom G6 was not yet available).

Comparator: sensor-augmented pump (user's own) and a Dexcom G5 CGM.

Key outcomes

In the 3 days of home device usage, time in target blood glucose range (70 mg/dl to 180 mg/dl) was improved in the closed-loop group compared with the control (closed loop: 71.0% plus or minus 6.6%; control: 52.8% plus or minus 13.5%; p=0.001). The mean glucose was 152.2 mg/dl (plus or minus 13.8 mg/dl) in the closed-loop group compared with 180.2 mg/dl (plus or minus 23.1 mg/dl; p=0.003) in the control. There was a reduction in hyperglycaemia exposure in the closed-loop group compared with the control group and no differences in hypoglycaemia exposure. A survey of device usability found that the closed-loop system was viewed favourably by the users.

Strengths and limitations

There were equal demographics and baseline diabetes control between the groups. Power calculations deemed the sample size to be sufficient to detect a true difference. However, this study was funded by the company and was only done over a 3-day period.

Forlenza et al. (2018)

Study size, design and location

Multicentre 6-week randomised crossover trial of 103 people with type 1 diabetes in the US. The trial consisted of 2 × 3-week periods when people were randomly assigned to use the predictive low-glucose version of the pump during 1 period and the non-predictive low-glucose version during the other.

Intervention and comparator(s)

Intervention: closed-loop system comprised of t:slim X2 pump with Basal-IQ integrated with a Dexcom G5 sensor and predictive low-glucose suspend technology.

Comparator: sensor-augmented pump comprised of t:slim X2 pump with Basal-IQ integrated with a Dexcom G5 sensor without predictive low-glucose suspend technology.

Key outcomes

Mean time in range (70 mg/dl to 180 mg/dl) increased in the intervention arm compared with the control arm (64% at baseline, 65% with intervention, and 63% with control; $p<0.001$). There was a reduction of time in hypoglycaemia ($p<0.001$) in the intervention arm compared with comparator. No one in the trial experienced severe hypoglycaemia or diabetic ketoacidosis during the intervention period. There was 1 severe hypoglycaemic event reported in the control period. A system usability survey stated that people would like to continue using the device with predictive low-glucose functionality and stated that it was straightforward to use.

Strengths and limitations

This was a well-powered randomised crossover study. However it only compared the predictive low-glucose suspend technology rather than comparing the t:slim X2 pump with a comparator device. This study was funded by the company.

Pinsker et al. (2020)

Study size, design and location

Retrospective analysis of 6,170 t:slim X2 pump users before and after installing the Basal-IQ software update with predictive low glucose suspend system in the US.

Intervention and comparator(s)

Closed-loop system comprised of t:slim X2 pump with a compatible CGM before and after using Basal-IQ with the predictive low-glucose suspend system.

Key outcomes

Time in range (70 mg/dl to 180 mg/dl) increased from 57.8% to 58.5% (0.64, 95% CI 0.04 to 1.24; p<0.001) and time in which blood glucose was less than 70 mg/dl decreased from 2.14% to 1.18% (-1.01, 95% CI -0.97 to -1.05; p<0.001) after installation of the Basal-IQ software. Of the 1,301 subjects in which 9 months of follow-up data was available, time in which blood glucose was less than 70 mg/dl remained at 1.2% and time in range was 62.6% (plus or minus 16.6%).

Strengths and limitations

This was a retrospective study using data submitted to an online diabetes management platform. Although there was a large study group, this analysis was funded by the company and verified independently.

Ekhlaspour et al. (2019)

Study size, design and location

Randomised controlled trial of 48 children and young people (aged 6 years to 18 years) participating in a 48-hour ski camp in the US.

Intervention and comparator(s)

Intervention: closed-loop system comprised of a t:slim X2 insulin pump with Control-IQ

and both a Dexcom G6 and G5 CGM.

Comparator: sensor-augmented pumps with low-glucose suspend technologies deactivated and a Dexcom G5 CGM.

Key outcomes

The Control-IQ system led to a 12% increase in time in range (70 mg/dl to 180 mg/dl) from 53.9% (plus or minus 24.8%) in the control group to 66.4% (plus or minus 16.4%) in the Control-IQ group (p=0.01). There was a 15% reduction of time spent in hyperglycaemia (above 180 mg/dl) in Control-IQ group compared with the control group (31.4%, plus or minus 17.6%, compared with 43%, plus or minus 24.5%; p=0.015). There was no difference in the time in hypoglycaemia or the amount of carbohydrate treatments for hypoglycaemia between the groups. There were no adverse events in either group.

Strengths and limitations

This randomised controlled trial, although only done over 48 hours, studied the efficacy of the pumps with prolonged intense activity. Remote monitoring by clinicians could have led to improved glycaemic control compared with real-world usage. The study was partially funded by the company.

Sustainability

The company claims the technology will reduce environmental impact with use of a rechargeable battery for the pump, which can last up to 7 days. It can also be charged without interrupting insulin delivery using existing or supplied mini USB cables. There is no published evidence to support these claims.

Recent and ongoing studies

- AIDE T1D RCT: automated insulin delivery in the elderly with type 1 diabetes. ClinicalTrials.gov identifier: NCT04016662. Status: not yet recruiting. Indication: type 1 diabetes. Devices: Tandem t:slim X2 with HCL or PLGS features. Date: April 2022. Country: US.

- AIR-CGM RCT: assessment of the impact of real-time continuous glucose monitoring in people presenting with severe hypoglycaemia. ClinicalTrials.gov identifier: NCT03748433. Status: active, not recruiting. Indication: type 1 diabetes, hypoglycaemia unawareness, hypoglycaemia. Devices: Dexcom G6 CGM, Tandem t:slim X2 Insulin Pump. Date: September 2020. Country: UK.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 5 experts were familiar with the technology and 4 had used this technology before.

Level of innovation

All experts viewed the device as an improvement to standard care when combined with a G6 continuous glucose monitor (CGM). One expert thought it was innovative specifically with the additional use of the Control-IQ software. Four of the experts mentioned improvements because calibration (using finger prick testing) is not needed for the G6 CGM. Two experts mentioned the increased accuracy of this CGM. The other advantages of this device listed were the reduced size of the pump, larger touch screen and the ability to remotely update software.

Potential patient impact

All experts thought that the increased time within glucose target range was the main benefit of the t:slim X2 insulin pump and CGM system. All experts thought that this system would improve quality of life and 2 experts noted that it would reduce the burden of diabetes self-management. Two experts mentioned that education in device usage and diabetes care is also a key factor in improving diabetes management.

The experts thought that this device would mostly benefit people with recurrent severe hypoglycaemia or those who lack hypoglycaemia awareness. It could also benefit other groups of people including those who are unable to maintain glucose control despite using either a CGM or insulin pump in isolation; those showing signs of developing diabetic complications; young people who may have changing basal insulin requirements; and to

support optimal glucose for people awaiting pancreas or islet transplantation.

Potential system impact

Overall, experts thought that better diabetes self-management would lead to a reduced burden on the NHS. This includes reduced outpatient attendance; fewer emergency admissions and ambulance call outs; as well as reducing future diabetes-related complications.

Two of the experts thought this technology would cost less than standard care and 1 expert thought it would be cost neutral in the long term because of potential reductions in diabetic complications. One expert thought it would cost less or the same depending on whether the long-term effect of manging HbA1c levels led to reduced diabetic complications. One expert thought it would cost more than standard care as insulin pumps with or without CGMs are not currently routinely used for all patients.

Two experts felt there would be no current resource impact because the proportion of patients with insulin pumps is currently low. Two experts stated there would need to be an increase in healthcare staff and education to implement widespread use of an insulin pump. This would be in addition to increased administrative support to maintain patient records and data. One expert suggested that the technology is best started in specialised centres to gain experience in supporting patients.

No safety issues were identified by the experts, aside from the general risk of hyperglycaemia from insulin pump use.

General comments

The experts commented that they have had positive experiences with the technology. However, they did mention that the uptake is limited by the criteria for accessing CGMs and insulin pumps on the NHS. As a result, some patients chose to buy their own pumps or CGMs. All experts suggested that this technology should be in addition to standard care. Some experts noted that different treatment options should remain available to allow for patient choice. Although all studies included were done in the US, this is similar to studies for other insulin pumps.

Patient organisation comments

Representatives from 2 patient organisations, Diabetes UK and JDRF, gave the following comments.

There are benefits in using this insulin pump with CGM for people with limited hypoglycaemia awareness and those who experience frequent hypoglycaemia. The opportunity to update software remotely is a useful part of the pump features and enables people with type 1 diabetes to have access to the most up-to-date features. Being able to send data through the cloud to clinicians is also helpful when optimising diabetes management. People with type 1 diabetes also found that using this device has had a positive impact on their mental health because they are less worried about variability in controlling glucose levels.

This smaller size of the t:slim X2 device was also thought to reduce stigma surrounding diabetes management, especially as people with type 1 diabetes do not want to be defined by their condition.

Some disadvantages were highlighted for insulin pumps in general. These include site infection linked to the cannula, diabetes burnout because of the learning needed to use the pump, and that the pumps are attached to an individual most of the time. In relation to the t:slim X2 pump, some users may find the touch screen intuitive, while others are prevented from using it because of a disability. Older people who have reduced dexterity may struggle with the size of the pump.

It was also highlighted that there is potentially regional variability in device access and education. People from lower socioeconomic backgrounds are less likely to have an insulin pump and have a higher risk of type 1 diabetes complications.

Expert commentators

The following clinicians contributed to this briefing:

- Professor Nick Oliver, professor of human metabolism and consultant in diabetes and endocrinology, Imperial College Healthcare NHS Trust. Participant in advisory boards for Medtronic Diabetes and Roche Diabetes GmbH. Received research funding for investigator-initiated clinical studies from Dexcom and Roche Diabetes GmbH.

- Dr Pratik Choudhary, professor of diabetes, University of Leicester. No conflicts declared.
- Dr Niall Furlong, consultant physician, diabetes and endocrinology, St. Helens and Knowsley Teaching Hospitals NHS Trust. No conflicts declared.
- Dr Parth Narendran, reader in diabetes medicine, Honorary Consultant Physician, Institute of Immunology and Immunotherapy College of Medical and Dental Sciences, University of Birmingham. No conflicts declared.
- Dr Jackie Elliott, clinical lead for diabetes, senior clinical lecturer and honorary consultant, Sheffield Teaching Hospitals NHS Trust. No conflicts declared.

Representatives from the following patient organisations contributed to this briefing:

- Diabetes UK
- JDRF.

Development of this briefing

This briefing was developed by NICE. NICE's interim process and methods statement for the production of medtech innovation briefings sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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