

# Implementation Toolkit

## Episcissors-60



## Introduction

NHS England's Innovation and Technology Tariff (ITT) went live on 1 April 2017. This new Tariff was introduced to incentivise the adoption and spread of transformational innovation in the NHS. The first two-year ITT runs from 2017 to 2019, with six themed product types identified as being suitable for at-scale introduction in the NHS and likely to result in great benefits for patients.

Four innovations on the NHS Innovation Accelerator (NIA) - an NHS England initiative supported by England's 15 Academic Health Science Networks (AHSNs) - meet the required theme specifications of the ITT.

These are: myCOPD, the Non-Injectable Arterial Connector (NIC), PneuX Prevention System, and Episcissors-60. Under the ITT, the first three innovations are funded under a zero cost model. Providers order the innovations directly from the supplier at no cost and NHS England reimburses the supplier directly. Episcissors-60 can be ordered via NHS Supply Chain, with providers reimbursed based on use.

In parallel, but separately from the ITT, NHS England is centrally funding the purchase of mobile ECG technology. A further NIA innovation, AliveCor's Kardia, meets the stringent specification of this technology, which will be available and managed via the AHSN Network.

The NIA has produced Implementation Toolkits for Episcissors-60, myCOPD, the Non-Injectable Arterial Connector (NIC), PneuX Prevention System, and AliveCor's Kardia. These toolkits detail how the innovations provide solutions to key challenges within our healthcare system; impact and outcomes, including cost savings, patient benefit and organisational advantage; an evidence summary and supporting testimonials; plus an overview of how to procure each innovation, including payment/price detail.

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## Introducing the NHS Innovation Accelerator (NIA)

The NHS Innovation Accelerator (NIA) is an NHS England Initiative delivered in partnership with the Country's 15 Academic Health Science Networks (AHSNs), hosted by UCLPartners. It supports delivery of the *Five Year Forward View* by accelerating uptake of high impact innovations for patient, population and NHS staff benefit, and providing real time practical insights on spread to inform national strategy.

Fellows supported by the NIA all share a set of values and passion for scaling evidence-based innovation to benefit a wider population, with a commitment to share their learnings. Some impressive results have been achieved by the NIA 25 Fellows in their first 20 months since July 2015, with 469 additional NHS commissioners and providers now using NIA innovations; £28.6m in external funds secured; 14 awards won; 51 jobs created; and ten innovations selling internationally. In addition, impact data is already available at adopter sites which demonstrates earlier intervention, reductions in complications and emergency admissions, alongside cost savings.

The NIA hosts 25 Fellows representing 26 innovations aimed at: activating people to self-manage; earlier intervention; long term conditions management and improving safety. The next NIA call, to be launched in June 2017, will select innovations that address the population challenges prioritised within the 44 Sustainability and Transformation Partnerships (STPs).

**For more information about the NIA, email [NIA@uclpartners.com](mailto:NIA@uclpartners.com)**

## An overview of the Innovation and Technology Tariff (ITT)

The Innovation and Technology Tariff (ITT) has been introduced to incentivise the adoption and spread of transformational innovation in the NHS.

Introducing new innovative products to the NHS can often be hampered by the need for multiple local price negotiations. The ITT aims to remove this need, while guaranteeing that local NHS organisations will be reimbursed for the costs of purchasing an ITT-approved product type. At the same time, the ITT allows NHS England to optimise its purchasing power and negotiate national 'bulk buy' price discounts wherever possible on behalf of the whole NHS.

The first two-year ITT runs from 2017 to 2019. This first Tariff has been developed as a pathfinder, with six themed product types identified as being suitable for at-scale introduction in the NHS, and likely to result in great benefits for patients.

The ITT themes are:

- Guided mediolateral episiotomy to minimise the risk of obstetric anal sphincter injury
- Arterial connecting systems to reduce bacterial contamination and the accidental administration of medication
- Pneumonia prevention systems which are designed to stop ventilator-associated pneumonia
- Web-based applications for the self-management of chronic obstructive pulmonary disease
- Frozen Faecal microbiota transplantation (FMT) for recurrent *Clostridium difficile* infection rates
- Management of Benign prostatic hyperplasia as a day case

The ITT operates under a zero cost model for four of the six themes, which allows providers to order ITT innovations without the need for multiple financial transactions. The zero cost model has been established to minimise the number of transactions and create a more efficient system to administer across the NHS. Both the 'guided mediolateral episiotomy to minimise the risk of obstetric anal sphincter injury' and 'the Management of Benign prostatic hyperplasia as a day case' operate under separate arrangements.

### Mobile ECG Technology

In parallel, but separately from the tariff, NHS England is centrally funding the purchase of mobile ECG technology to improve diagnosis of atrial fibrillation (AF). Taking repeat ECG recordings continuously over a 24-hour period or recording events over several days can increase the probability of detecting an arrhythmia, but needs small, portable ECG machines to be practical. The availability of this technology will be managed through the Academic Health Science Networks (AHSNs).

**The NHS England Innovation and Technology Tariff 2017-2019 Technical Notes is available to download at: [www.england.nhs.uk/resources/pay-syst/development/tech-tariff-17-19-technical-notes/](http://www.england.nhs.uk/resources/pay-syst/development/tech-tariff-17-19-technical-notes/)**

## Introducing Episcissors-60

### Challenge/problem identified

Each year 30,000 women across the UK suffer obstetric anal sphincter injuries (OASIS). This is often due to misjudging the angle of surgical cuts during childbirth.

Episiotomy angle is a crucial factor in causation of OASIS. Sutured episiotomies angled too close to the midline (<30 degrees) or too far from the midline (>60 degrees) fail to unload the perineum sufficiently and predispose women to OASIS. OASIS is a serious complication and is the single most important cause of anal incontinence (AI) in women.

With over 15% of all births in England needing an episiotomy<sup>7</sup>, there is a clear unmet clinical need to reduce incidence of OASIS and to protect young mothers from avoidable harm which can have a devastating impact on their lives.

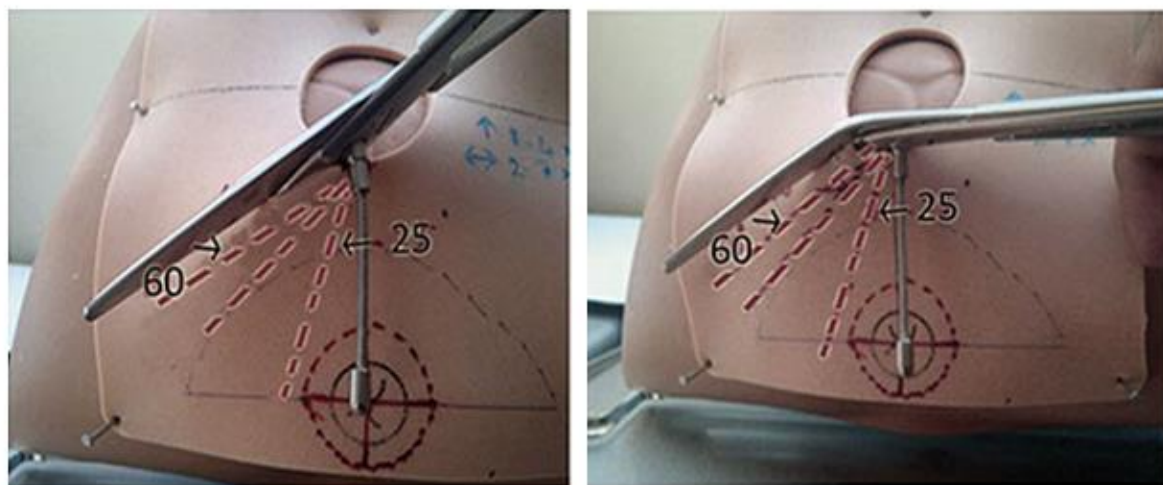
### The solution

Episcissors-60 are simple to use surgical scissors, guiding an accurate mediolateral episiotomy at 60 degrees, and therefore removing human error in estimating episiotomy angles during childbirth [FIGURE I.]. This product has proven clinical efficacy and is safer than letting women tear spontaneously in first normal births.

The angle of the cut is important and the Royal College of Obstetricians and Gynaecologists (GTG29)<sup>6</sup> recommends that cuts need to be at 60 degrees to reduce the incidence of poor patient outcomes, reconstructive surgery and litigation costs. The use of the angled scissors in episiotomies therefore should improve patient experience and outcomes. Episcissors-60 offers substantial NHS cost savings whilst transforming outcomes for thousands of mothers each year.

Episcissors-60 can be used in secondary care midwifery and obstetric units, primary care midwifery units or birth centres, and during home births.

FIGURE I.



## Impact and outcomes

### Key statistics

- Of the women requiring episiotomies, around 25% experience OASIS
- Episcissors-60 has reduced OASIS in women by up to 50% in five UK NHS hospitals
- Results at London-based Trusts have, for example, shown a reduction in OASIS in instrumental births down from 8.8% to 0.6% and in normal births down from 4.3% to 0%
- Since being part of the NIA, Episcissors-60 has been adopted by 15 UK hospitals, including Liverpool Women's NHS Foundation Trust; Wrightington, Wigan and Leigh NHS Foundation Trust; Norfolk and Norwich University Hospitals NHS Foundation Trust; the Royal Free London NHS Foundation Trust; University College London Hospitals NHS Foundation Trust; Frimley Health NHS Foundation Trust; University Hospitals Coventry and Warwickshire NHS Trust; Northampton General Hospital NHS Trust; and Chelsea and Westminster Hospital NHS Foundation Trust
- The cost of OASIS to the NHS is approximately £57 million annually, including repair (£1,625 per patient), elective caesarean sections and litigation costs

### Impact Modelling Tool

The NIA has developed an Impact Modelling Tool to provide an indication of the savings that could be achieved through implementation of Episcissors-60.



Episcissors60\_economicmodelling.xlsx

### Testimonials

*"I would not want to deliver in a London hospital that does not use the Episcissors-60."*

Patient

*"After the introduction of Episcissors-60, we found that 86% of doctors and 100% of midwives were able to achieve post-suturing angles between 40 degrees and 60 degrees... user feedback showed high rates of satisfaction in using Episcissors-60 among all users."*

Van Roon et al (2015), International Journal of Women's Health

*"Of all the improvements in obstetrics in the past 20 years, this truly stands out for its simplicity and effectiveness"*

Professor of Obstetrics, Dublin

## How to procure Episcissors-60

The below is detailed within The NHS England Innovation and Technology Tariff 2017-2019 Technical Notes, available to download at:

[www.england.nhs.uk/resources/pay-syst/development/tech-tariff-17-19-technical-notes/](http://www.england.nhs.uk/resources/pay-syst/development/tech-tariff-17-19-technical-notes/)

### Payment/price detail

NHS England will pay £16 per patient to NHS providers who implement this innovation. This price, which is based on an estimate of 20 uses, should cover the costs of the purchase of Episcissors-60 within the first year. The £16 per patient use price will be reimbursed by NHS England on a quarterly basis based on recorded evidence of use. Refer to page 10 of the ITT Technical Notes for reporting instructions.

### Availability

The Department of Health have centrally procured a number of angled episiotomy scissors and once there is agreement between providers and commissioners on usage, providers may purchase the appropriate product via the NHS Supply chain website.

For this theme NHS England will reimburse providers £16 per patient use.

Order from NHS Supply Chain: <http://my.supplychain.nhs.uk/Catalogue/product/fcc454>



## Evidence summary

- Comparison of obstetric anal sphincter injuries in nulliparous women before and after introduction of Episcissors-60 at two hospitals in the UK (Van Roon et al, 2015, International Journal of Women's Health), indicated most healthcare professionals achieved post-suturing episiotomy angles between 40 degrees and 60 degrees; a statistically significant reduction in OASIS in nulliparous spontaneous vaginal deliveries; high rates of satisfaction among all users( Episcissors-60 rated as 'good' to 'very good' by 84% of users)<sup>3</sup>.
- Obstetric anal sphincter injuries after episiotomy: systematic review and meta-analysis (Verghese et al, 2016, International Urogynecology Journal): this research study concluded that the pooled analysis of a large number of women undergoing vaginal birth, most of who were nulliparous, indicates that mediolateral episiotomy (MLE) has a beneficial effect in prevention of OASIS. An accurately given MLE might have a role in reducing OASIS and should not be withheld, especially in nulliparous women<sup>2</sup>.
- National Institute of Health and Care Excellence (NICE) evaluation of Episcissors-60: average post-delivery suture angle of 50 degrees - no cases of OASIS reported; comparison of the angled version of Episcissors-60 with the Braun-Stadler scissors demonstrated a clear difference of 12 degrees in post-delivery suture angles. One case of OASIS was reported in the Braun-Stadler group, none were reported in the Episcissors-60 group<sup>5</sup>.
- NICE recommended a 45-60 degree episiotomy in their intra-partum guidance in 2007<sup>5</sup>.
- The Episcissors-60 were developed after consultations with 15 perineal trauma experts from the UK and Europe in response to this significant 'unmet clinical need'. Two designs were unanimously selected from eight prototypes by these experts. Early studies were published in the peer-reviewed scientific literature (Freeman et al 2014, Patel et al 2014)<sup>4</sup>.
- Episcissors-60 have now been acknowledged in the RCOG guidance as being effective in achieving the correct angle. This is the apex guidance on the topic in the UK. RCOGGT29, peer-review draft October 2014<sup>6</sup>.

## References

1. Lou YY, Thakar R, Sultan AH, Ajay B. Does Episcissors-60 reduce the incidence of obstetric anal sphincter injuries (OASIS)? Croydon University Hospital, UK. BJOG An International Journal of Obstetrics and Gynaecology ([www.bjog.org](http://www.bjog.org))
2. Verghese TS, Champaneria R, Kapoor DS, Latthe PM. Obstetric anal sphincter injuries after episiotomy: systematic review and meta-analysis. *Int Urogynecol J*, 2016 27: 1459-1467 ([springerlink.com](http://springerlink.com))
3. Van Roon et al. Comparison of obstetric anal sphincter injuries in nulliparous women before and after introduction of the Episcissors-60 at two hospitals in the United Kingdom. *International Journal of Women's Health*, 2015: 7 949-955
4. Freeman RM, Hollands HJ, Barron LF, Kapoor DS. Cutting a mediolateral episiotomy at the correct angle: evaluation of a new device, the Episcissors-60. *Medical Devices: Evidence and Research*, 2014: 7 23-28
5. National Institute for Health and Care Excellence (NICE), Clinical Guidance [CG190], Intrapartum care for healthy women and babies. Last updated: February 2017  
<https://www.nice.org.uk/guidance/CG190>
6. Royal College of Obstetricians and Gynaecologists (RCOG), Guidance [GTG29], Peer Review Draft, October 2014
7. NHS Maternity Statistics 2011-12 Summary Report, 2012. The Health and Social Care Information Centre, Hospital Episode Statistics  
<http://content.digital.nhs.uk/catalogue/PUB09202/nhs-mate-eng-2011-2012-rep.pdf>

## Contact information

### Episcissors-60

E: [dharmesh.kapoor@medinvent.net](mailto:dharmesh.kapoor@medinvent.net)

### NHS Innovation Accelerator (NIA)

E: [NIA@uclpartners.com](mailto:NIA@uclpartners.com)

W: [www.england.nhs.uk/ourwork/innovation/nia/](http://www.england.nhs.uk/ourwork/innovation/nia/)

### NHS Innovation and Technology Tariff (ITT)

E: [innovation.england@nhs.net](mailto:innovation.england@nhs.net)

W: [www.england.nhs.uk/resources/pay-syst/development/tech-tariff-17-19-technical-notes/](http://www.england.nhs.uk/resources/pay-syst/development/tech-tariff-17-19-technical-notes/)

# NHS Innovation Accelerator