

National Institute for Health and Care Excellence
Medical technologies evaluation programme
MT476 UroShield for preventing catheter-associated urinary tract infections

Consultation comments table

There were 112 consultation comments from 19 consultees:

- Patients: 39 comments
- Company: 25 comments
- Health and social care professionals: 19 comments
- Members of the public: 21 comments
- Healthcare researcher: 7 comments
- Medicines and Healthcare products Regulatory Agency (MHRA): 1 comment

The comments are reproduced in full, arranged in the following themes:

- Recommendations (comments 1 to 10)
- The technology (comments 11 to 17)
- Care pathway (comments 18 to 20)
- Intended use (comments 21 to 24)
- Patient selection (unmet need) (comments 25 to 32)
- Clinical evidence (comments 33 to 35)
- Patient benefits (comments 36 to 51)
- Cost modelling (comments 52 to 69)
- Further research (comments 70 to 74)
- Consultation question response (comments 75 to 90)

One consultee also provided 22 comments stating, 'No comment' or 'N/A'. These have not been included in the table below.

#	Consultee ID	Role	Section	Comments	NICE responses
Recommendations (n=10)					
1	1	Member of the public	1.1	This is a very disappointing conclusion, for my father [REDACTED] UroShield has undoubtedly been hugely beneficial. It has greatly improved his comfort and quality of life, to such a degree that I believe it would easily justify an additional cost. However it has also reduced his need for district nurse appointments, ambulance callouts and hospital stays resulting from catheter-related issues that it must surely represent a net saving in the cost of his treatment. I very much hope this conclusion can be revisited and reversed as soon as possible, so this excellent new treatment can be made available to him and others in his position.	<p>Thank you for your comment.</p> <p>The committee values comments about the experiences of people who have used the technology.</p> <p>The committee carefully considered the evidence available for this technology and concluded that although UroShield shows promise there is currently not enough evidence to make a positive recommendation.</p> <p>If a technology is recommended for use in research, the recommendations are not intended to preclude the use of the technology but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.</p>
<i>Recommendations – patient selection</i>					
2	2	Patient	1.1	i would say that in my experiance it has been a help , what has not been taken into consideration with in the wording of this statment is the fact that everybody is an individual. The device may work well for myself but not everybody .	<p>Thank you for your comment.</p> <p>The committee values comments about the experiences of people who have used the technology.</p> <p>The committee discussed this comment and agreed that the technology is not suitable for everyone. This is reflected in section 4.7 of the guidance.</p>
3	6	Member of the public	1	Whilst I agree routine adoption on the whole population, I do think that this should be recommending as a trail on all patients whom those who suffer with chronic CAUTI, are repeatedly	Thank you for your comment.

				<p>admitted to hospital, taking regular antibiotics, having frequent blockages and catheter changes.</p> <p>this is a very small population however the impact of UroShield on this small population has shown considerable benefits to patient health and quality of life, along with cost avoidance from emergency admissions, ambulance and transport costs, along with decrease in antibiotics.</p>	<p>The committee has carefully considered the evidence and the input from the patient and clinical experts. It concluded that UroShield shows promise but there is currently not enough evidence to make a positive recommendation. The EAC noted that from a clinical perspective, the evidence is very limited and there are no patient groups identified other than short term versus long term catheterization. Further research is recommended to identify if specific patient groups may benefit from using UroShield.</p>
4	6	Member of the public	Rationale	<p>If standard care has proven to fail for a small population of long term indwelling catheter patients, I believe uroshield should be recommended for trial at this stage.</p>	<p>Thank you for your comment.</p> <p>Please see NICE's response to comment 3.</p>
5	6	Member of the public	2.3	<p>really clear aspects here, however as previously status there are a small population where this is not adequate and these patients are the ones where this needs to be the recommended choice.</p>	<p>Thank you for your comment.</p> <p>Please see NICE's response to comment 3.</p>
6	6	Member of the public	4.2	<p>the sample size will always be small, as this device is most suitable and most effective in a very small patient population, I believe if recommended for use in this population then greater benefits will be seen. The quality of life of these patients needs to be considered, and how this will improve other comorbidities like their mental health.</p>	<p>Thank you for your comment.</p> <p>Please see NICE's response to comment 3.</p>
7	15	Company	1.1	<p>We would ask the committee to recommend the use of UroShield for a small group of selected patients with long-term (lifetime) catheters at high risk of UTIs and other catheter-related problems who have demonstrated that they are in the greatest need for UroShield.</p> <p>This will enable continuous use for the existing and growing number of NHS patients using UroShield, who are concerned that they may not be able to have future use of the device. Ideal Medical Solutions have been funding many of these patients for up to 3 years and this cannot be sustained, so if UroShield is not made available through the NHS, payment for the devices will</p>	<p>Thank you for your comment.</p> <p>Please see NICE's response to comment 3.</p>

				<p>need to be borne by the patients themselves whilst the NHS Trusts develop business cases for each patient.</p> <p>Northamptonshire CCG, who are aware of the NICE Guidance submission, have recently contacted us to commence discussions regarding the supply of UroShield to at risk patients and we are engaging with their pharmacy team who are requesting that we apply for UroShield to be made prescribable through FP 10.</p> <p>The NHS Supply Chain has engaged in a market engagement activity with potential providers on an operating model to supply UroShield to patients by publishing the Prior Information Notice (PIN).</p> <p>Based on the evidence presented for the community patients at high risk and the evidence reported by Smith et al (2019), we estimate this small, high risk group of NHS long term catheter users to be between 5% and 10% of the 90,000 patients who live with long term catheters. The EAC also reported that for this group of high risk patients, the device would always be cost saving.</p> <p>Although many patients in hospital care can benefit from UroShield, we agree that evidence for short term users in hospitals is limited, and more evidence will reduce uncertainties.</p>	
8	15	Company	4.8	<p>We agree with this overview and encourage the committee to recommend UroShield for patients with a long-term catheter with recurrent UTI and blockages in the community who clinicians select as being able to benefit most from the device.</p> <p>NHS England reported in 2014 that urinary tract infections (UTIs) were the condition with the highest emergency admissions rates (NICE 2018). Of these UTIs, between 43% and 56% were associated with a urinary catheter (Loveday et al 2014). With 10% of residents in care homes and 15-25% of hospital inpatients using a long-term catheter, the likelihood of these patients developing a catheter associated urinary tract infection (CAUTI) is considerably increased</p>	<p>Thank you for your comment.</p> <p>Please see NICE's response to comment 3.</p>
<i>Recommendations - research</i>					
9	2	Patient	1.2	<p>I understood that by adopting the trials at portsmouth/southhampton that would address this issue</p>	<p>Thank you for your comment.</p>

					The committee considered the aims of the ongoing study by the University of Southampton and concluded that while it would provide additional evidence on patient experiences and the effect of UroShield on the microbiota in the urine, it is not a comparative study and therefore will not resolve the uncertainties in effectiveness. Further research is therefore recommended.
10	15	Company	1.2	We appreciate that further evidence will reduce uncertainties about the effectiveness of UroShield. However, the significant impact that the device is already having on the lives of long-term catheter users is evident to the patients, carers and clinicians who witness the improvement in the quality of life of the patients. We welcome the opportunity to engage in further research in hospital settings and appreciate the research guidance that has been provided.	Thank you for your comment. The committee carefully considered the evidence and the anecdotal benefits described by patients and the clinical experts. It concluded that UroShield shows promise but there is currently not enough evidence to make a positive recommendation in any specific patient groups.
The technology (n=7)					
11	1	Member of the public	4.6	The rechargeable battery pack which the patient expert uses is commonly described as a "USB power bank", more typically used to top up mobile phones when travelling. They are widely and cheaply available, and convenient to carry. Although improved battery life would be a useful enhancement for future development of the UroShield, it need not be considered a major issue for the purposes of this review.	Thank you for your comment. The battery life of UroShield was discussed by the patient and clinical experts, as well as the patient survey. It was not a major factor in the committee considerations which focussed on the limited clinical evidence on the technology.
12	2	Patient	2.1	i do understand the basic principal of the device and it does make sence when applied . in my experiance it does do what they claim .	Thank you for your comment. The committee values comments about the experiences of people who have used the technology.
13	2	Patient	2.2	the only comment i can make with regards to the power pack is that it could be made a little more robust .	Thank you for your comment.

					The committee values comments about the experiences of people who have used the technology.
14	2	Patient	2.4	i have no knowladge in this area but believe that i must be quiet simple to independantly verify the companies claims in a hospital labouarotry	Thank you for your comment. The committee values comments about the experiences of people who have used the technology.
15	15	Company	4.6	Many patients who have long term catheters use them for the rest of their lives and by their nature, the catheters and collection devices reduce the mobility of the patients. For these patients, the battery life is less significant as they are easily able to connect to the mains power supply. Feedback from patients who are more ambulant and particularly the patients who use UroShield with their suprapubic catheters have requested a longer battery life. Some use a power pack when they are travelling for longer than the 6.5 hours that the battery allows. The company is addressing this need for longer battery life as it will be a significant improvement for the more ambulant patients.	Thank you for your comment. Please see NICE's response to comment 11.
16	17	Healthcare researcher	3.9, 4.1, 4.2	It is clear this device does not suit everyone and, although most are reporting less debris and improved flow of urine through the catheter, not all wish to continue using it. The main reasons for this are centred around the connectors for the charging unit and the actuator, which are described as fiddly and difficult to manipulate – especially for those with neurological conditions where manual dexterity is compromised. The general nuisance of carrying the device is cited as a common deterrent and the low-level hum of the device has been described as embarrassing for some and annoying for others. Trailing wires are another worry.	Thank you for your comment. The committee values comments from healthcare professionals and researchers about the experiences of people who have used the technology. The committee discussed this comment and agreed that the technology is not suitable for everyone. This is reflected in section 4.7 of the guidance.
17	19	MHRA	General	Dear [REDACTED] Our Reference: [REDACTED] Thank you for giving MHRA an opportunity to review the draft guidance for MT476 UroShield for preventing catheter-associated urinary tract infections.	Thank you for your comment.

				<p>Based on the information provided I have no comments on the section related to Regulatory information of the draft document.</p> <p>Please contact me if you want further clarification.</p> <p>Kind regards,</p> <p>█</p>	
Care pathway (n=3)					
18	10	Health and social care professional	2.3	<p>Catheter passports are the ideal but more often than not patients present to a busy A+E department for their catheter change once it is blocked and the passport is not completed and therefore is not a reliable record of catheter related issues. As patients may be triaged to different hospitals within their region, equally hospital records are not a truly reliable resource in catheter care.</p>	<p>Thank you for your comment.</p> <p>The committee acknowledged that section 2.3 describes recommended practice in standard care, but this may vary in everyday practice. It decided not to change the guidance.</p>
19	15	Company	4.7	<p>Catheter changes differ from one global healthcare system to another and there is also a difference in what is recommended in the pathway of care and what happens in the real world. Whilst It is recommended that the actuator is changed when the catheter is changed, the UroShield actuator is designed to continue operating effectively beyond the time when the catheter is required to be changed. This keeps the patient safe if there is a delay with the catheter change. In the US, catheter changes are every 30 days, however, in the NHS, it is 6 weeks and sometimes longer. The Instructions for Use presently recommends that the actuator is changed every 30 days and the company is presently addressing the technology and the life of the actuator to be healthcare system specific. The present actuator used by NHS patients meets the requirements of the pathway of care as use of the device in the UK was prioritised by the company when the NICE Guidance process commenced in 2019.</p>	<p>Thank you for your comment.</p> <p>The sections have been renumbered in the guidance and this is now section 4.8. This section describes the use of UroShield by the patients in the NHS for up to 6 weeks as well as the company's intention to make the technology more country specific. The committee decided not to change the guidance.</p>
20	15	Company	4.9	<p>This number of patients using UroShield has already increased since submission of the evidence as a result of th end of the lockdown and more NHS Trusts re-engaging with the company. We also anticipate expansion of use as the Southampton study reaches a conclusion, where existing study participants choose to continue using UroShield and further patients are added in</p>	<p>Thank you for your comment.</p> <p>The sections have been renumbered in the guidance and this is now section 4.10. This section has been amended to add</p>

				<p>that CCG region. If there is a care pathway for adoption and funding is made available, more clinicians will adopt to use UroShield with at risk patients, where other treatment options have failed.</p> <p>The NHS Supply Chain has engaged in a market engagement activity with potential providers on an operating model to supply UroShield to patients by publishing the Prior Information Notice (PIN).</p> <p>The UroShield device requires a minimum of training effort and in many cases, the patients and carers can manage the device themselves following training. In addition to the Instructions for Use and Quick Start Guide, an online video is available. Where health care organisations are using for the first time, training is made available through personal visits or scheduled online training sessions. When required, further support is available for clinicians, patients and carers through a specialist nurse advisor and helpdesk team. Ideal Medical Solutions have a dedicated customer service team who provide support to patients using the device. Plans are in place to resource this team further as the number of UroShield patients grow. In addition, Ideal Medical have an ex-intensive care nurse who has extensive knowledge of the issues experienced by patients with indwelling catheters and is able to support patient enquiries, assist other clinicians and offer site visits if necessary to support the use of UroShield. Additional nurses are planned to be employed by the company on a regional basis, as the number of UroShield patients increase.</p>	<p>information on the training and support available through the company.</p>
Intended use (n=4)					
21	2	Patient	2.5	this is understood and we are advised	Thank you for your comment.
22	10	Health and social care professional	2.5	Uroshield can also be used to reduce the number of catheter blockages not associated with recurrent urinary tract infections.	<p>Thank you for your comment.</p> <p>The committee values comments from healthcare professionals about their experience using the technology.</p> <p>The committee carefully considered the strong support from patients and healthcare professionals on the use of UroShield to prevent or reduce blockages.</p>

					It concluded that there is little clinical evidence, with only 1 study reporting blockages as an outcome. Further research is therefore recommended.
23	15	Company	2.1	From the feedback of patients and clinicians, we also want to emphasise that one of the first indications of UroShield working is that they notice a reduction or elimination of blockages in the catheter. This is often within the first weeks of the use of the device.	Thank you for your comment. Please see NICE's response to comment 22.
24	15	Company	2.5	UroShield is intended to reduce the risk of catheter-associated UTIs and catheter blockages in adults with urethral or suprapubic indwelling urinary catheters.	Thank you for your comment. Please see NICE's response to comment 22. The committee decided not to change the guidance to include blockages in section 2.5. This is in line with the technology's IFU which focusses on UTI. The potential benefit of UroShield in preventing or reducing blockages is described in other sections of the guidance document, including sections 4.1 and 4.5.
Patient selection (unmet need) (n=8)					
25	2	Patient	3.6	and they should be looked at separately	Thank you for your comment.
26	6	Member of the public	3.9	this highlights the small group of patients that have significant improved Quality of life with Uroshield and what we need to focus on.	Thank you for your comment. Please see NICE's response to comment 3.
27	15	Company	4.1	The clinical and patient experts and the committee explained clearly that the UroShield device addresses a significant unmet need, especially for people with long term catheters in the community, suffering with recurrent catheter related problems. However, we believe that the comment that "it is promising" is an understatement, as the expert statements and patients experiences, testimonies and data from patients, consistently demonstrates the clinical impact that UroShield has on their lives. Catheter care is limited in terms of new solutions to address well known problems with long term catheter use and	Thank you for your comment. The committee carefully considered the comments from the patient and clinical experts and consultees. It recognised that preventing catheter-associated UTIs and blockages is a significant unmet need, especially in people with long-term catheters in the community. It concluded that UroShield shows promise in

				<p>the issues of blocked catheters, CAUTI and antibiotic administration coupled with the pain and discomfort experienced by patients. Catheter related injuries continue to increase year on year in the NHS and the intervention of UroShield safely addresses this issue and will have an immediate, measurable impact on patient care.</p> <p>From the data and the combined experiences of NHS patients using UroShield, the risk associated with the use of long-term catheters is significantly lowered by using UroShield in conjunction with a catheter.</p>	<p>addressing this unmet need but there is currently not enough evidence to make a positive recommendation in any specific patient groups.</p>
28	15	Company	4.10	<p>The UroShield device has an excellent safety record with no reported device related adverse effects. Many of the NHS patients using UroShield have been using for over 2 years with some now in their 3rd year. Almost all patients using UroShield had explored every other treatment option, some of these patients have shared their positive feedback with the committee and explained that if the UroShield was not available to them, they know that it would have a devastating effect on their health and quality of life.</p>	<p>Thank you for your comment.</p> <p>The sections have been renumbered in the guidance and this is now section 4.11. This section has been amended to clearly state that UroShield is safe and without any significant device-related adverse events.</p>
29	16	Health and social care professional	Rationale	<p>In my group of patients (SCI patients) asymptomatic colonisation of bacteria is the biggest problem which can become symptomatic on any intervention.</p> <p>Using Uro Shield has reduced the incidence of symptomatic UTI and blockage of long term catheter.</p>	<p>Thank you for your comment.</p> <p>The committee values comments from healthcare professionals about their experience using the technology.</p>
30	16	Health and social care professional	4.8, 4.9	<p>In my opinion Uro shield can be used to improve quality of life by reducing recurrent UTI and blockage of catheters in patients with long term conditions after exploring all other treatment options.</p> <p>I will use Uro shield in specific group of patients with long term catheters where other options have been explored to manage recurrent blockage and urinary tract infections</p>	<p>Thank you for your comment.</p> <p>The committee values comments from healthcare professionals about their experience using the technology.</p>
31	17	Healthcare researcher	3.9, 4.1, 4.2	<p>From the anecdotal finding we have seen so far, it is apparent that the Uroshield device has had a marked beneficial effect of the quality of life of some participants, where no other options exist. For others it will take a longer trial to identify any if there are any potential long-term benefits. The device is not suitable for all and even if it is effective there will be some who cannot</p>	<p>Thank you for your comment.</p> <p>The committee values comments from healthcare professionals and researchers about the experiences of people who have used the technology.</p>

				use it for lifestyle and practical reasons. However, the Uroshield does present an additional option for those individuals whose lives are interrupted by frequent catheter blockage.	
32	17	Healthcare researcher	3.9, 4.1, 4.2	In conclusion our initial observations suggest that the Uroshield works well for some people and offers a rapid, high impact solution for a specific group of patients who suffer the indignity and disruption of frequent catheter blockage.	Thank you for your comment. The committee values comments from healthcare professionals and researchers about the experiences of people who have used the technology.
Clinical evidence (n=3)					
33	15	Company	4.2	The UK based real world study (da Silva) was suggested by the NICE Scientific team in December 2019 following their review of the data and was conducted during 2020, when the pandemic was having a major impact on patients and clinicians lives. The pandemic also delayed the start of the Southampton study so the real-world study of existing patients was the only means of collecting valuable patient data during that year. Despite the issues that the lockdown presented for patients, their carers and clinicians, this data was willingly provided. These patients have now become long term users of UroShield and the better quality of life that these patients are experiencing demonstrates the value of the device as an addition to standard care.	Thank you for your comment. The committee carefully considered the evidence and comments from the patient and clinical experts and consultees.
34	15	Company	4.3	The UroShield device was designed for continual use as most patients selected to use the device will be long term or lifetime users. The Markowitz et al RCT was undertaken in a relevant US population of patients with long-term indwelling catheters in a community setting and included relevant outcomes as detailed in the decision problem. The study was conducted according to FDA specific requirements using the active UroShield device and a comparator sham device in addition to standard care for 30 days followed by a 60 day follow up without the UroShield and sham device. This was because long term catheters are changed every 30 days in the US health system and the FDA required that the UroShield device needed to demonstrate a significant reduction in CFU counts and CAUTI during those 30 days for the treatment group measured against the follow up period of 60 days when the UroShield device was not present.	Thank you for your comment. The committee carefully considered the clinical evidence including the Markowitz et al (2018) RCT. The EAC noted that while the results of this study indicate lower CFU with Uroshield compared with the sham device, it cannot comment on whether this was because of the acoustic waves. The committee therefore concluded that more evidence is needed.

				<p>Significantly, the CFU count in the treatment group continued at a low level during that 60 day follow up period.</p> <p>Whilst we recommend that the UroShield device is attached to the catheter continuously, there will be occasions when the device needs to be removed for a short period of time for patient washing or clinical interventions. The results of the study indicate that the rate of reproduction and multiplication of bacteria with patients in the UroShield treatment group was significantly slower after the device was removed, than was observed in the control group.</p> <p>The acoustic waves are believed to alter the quorum sensing of the microbes, disrupting the signalling between cells which helps to delay and disrupt the formation of the biofilm and its extracellular matrix. It is believed that this environment, together with the ongoing acoustic assault of the acoustic waves on the microbes, generates the bactericidal effects of the UroShield device.</p>	
35	15	Company	4.4	<p>We agree with this conclusion and the ongoing Southampton study is examining the relationship between the measurement of bacteriuria and CAUTI rates in patients who have recurrent CAUTI and blockages. The CAUTI rates in Smith et al are presently the best available and they are supported by the EPIC 3 Guideline, which states that there is a direct link between bacteriuria and CAUTI, reporting that 30% of catheterised patients will develop bacteriuria between 2-10 days of catheterisation and 24% of these will develop symptomatic CAUTI (so approximately 7% of catheterised patients will develop symptomatic CAUTI by 10 days). The same Guideline also reports that there is a 5% day on day increase in bacteriuria such that by 30 days, almost all catheterised patients will develop bacteriuria with a 24% risk of developing symptomatic CAUTI.</p>	<p>Thank you for your comment.</p> <p>Section 4.4 has been amended to highlight the role of bacteria in catheter-associated UTI and blockages.</p>
Patient benefits (n=16)					
36	1	Member of the public	4.1	<p>The improvement to quality of life for my father [REDACTED] and mother (his carer) from using the UroShield has been enormous. My father previously contracted frequent UTIs resulting from catheter usage, typically two or three times per year. These made him extremely ill; in addition to the risk and discomfort normally associated with such infections,</p>	<p>Thank you for your comment.</p> <p>The committee values comments about the experiences of people who have used the technology. It carefully considered</p>


				<p>anything which causes an elevated temperature compounds with his Multiple Sclerosis to greatly worsen its usual symptoms. This leaves him needing round the clock care through an extended recovery period, provided either by a hospital stay or by my mother. These periods of exacerbated illness are distressing to my father, mother and the wider family. Periods of hospitalisation are stressful for all concerned, remove my father from the stability of known treatment and routines at home, and bring new risk of contracting hospital-acquired infections. Any home caring for my father during these periods places a huge strain on my mother, on top of her usual workload as his full time carer. The next instance of a UTI and all these associated issues was previously a constant "when, not if" threat hanging over the family, but in the three years using UroShield my father only experienced one instance of UTI, a great improvement and a huge relief to us all. With catheter blockages (which were previously a frequent and significant problem in addition to UTIs) also completely prevented during the time using UroShield, it feels like a major and unpredictable source of extra health issues to be managed on top of my father's MS has been resolved. It would be unthinkable to return to the way things were before trying UroShield, now that we know such an effective and simple solution exists.</p>	<p>these comments along with the evidence and expert advice.</p> <p>If a technology is recommended for use in research, the recommendations are not intended to preclude the use of the technology but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.</p>
37	1	Member of the public	4.5	<p>This point is key to the benefits which my father [REDACTED] experienced from UroShield. This review appears to focus primarily on reduction in UTIs, and bacteriuria levels as an indicator of UTI risk. However catheter blockages which do not lead to UTIs still cause considerable discomfort, progressing to intense pain if not treated promptly, plus stress and inconvenience to carers. Treatment consists of an uncomfortable catheter wash-out procedure, and often a full catheter replacement if that is not effective. It requires an unplanned district nurse callout when coverage is available, or an ambulance callout and hospitalisation when district nurse coverage is unavailable. The prevention of catheter blockages since my father began using UroShield is a major factor in the improvement it has brought to his quality of life, described as "transformational" by his GP. Catheter blockages were</p>	<p>Thank you for your comment.</p> <p>The committee values comments about the experiences of people who have used the technology. It carefully considered these comments along with the evidence and expert advice.</p> <p>Please see NICE's response to comment 3.</p>

				previously a frequent occurrence for him, but since starting to use UroShield he can remember no further instances.	
38	3	Health and social care professional	General	I have personal experience as a Urologists using this device on patients with permanent urinary catheter. The patients have far fewer infections, hospital admissions and frequency of catheter changes. This contributes immensely to their quality of life and greatly reduces the health care burden.	Thank you for your comment. The committee values comments from healthcare professionals about their experience using the technology.
39	4	Member of the public	General	My husband was diagnosed with MS some 47 years ago. We have coped with all the problems that has brought, but the worst aspect for the last number of years has been UTIs and catheter blockages. UTIs in particular have a devastating effect which usually require an ambulance and a hospital stay and impact on his MS symptoms. Catheter blockages again require an ambulance to A&E or occasionally are dealt with by a District Nurse. For quite some time my husband was subjected to weekly catheter washouts, which very rarely if ever worked and would result in the catheter being changed yet again. He also took prophylactic antibiotics to try and ease the number of UTIs. I urge NICE to make UroShield available to all those who would benefit from it. The benefits of this ultrasound device are simply life changing and this consultation document also confirms that another benefit is a cost saving and staff time saving for the NHS which has to be applauded.	Thank you for your comment. The committee values comments about the experiences of people who have used the technology. It carefully considered these comments along with the evidence and expert advice. Please see NICE's response to comment 3.
40	5	Patient	General	I'm a patient with a Suprapubic catheter fitted, I've got Spina Bifida and Hydrocephalus. I've been using the Uroshield Device on a trial period. Since using the Uroshield Device I've been experiencing a lot less catheter blockages, in fact, minimal blockages. Previous to using the Uroshield Device I was experiencing catheter blockages every other day!! This device and the treatment it's giving me is life changing!! The Uroshield Device has given me my freedom & confidence back, so I would like to take this opportunity to say thank you for allowing me to trial this wonderful product. The issue that I'm having now is, my trial has nearly ended, and I CANNOT be without this device and revert back to what I was experiencing before as I'm highly susceptible to Urosepsis	Thank you for your comment. The committee values comments about the experiences of people who have used the technology. It carefully considered these comments along with the evidence and expert advice. Please see NICE's response to comment 3. If a technology is recommended for use in research, the recommendations are not intended to preclude the use of the

				<p>(which I've had before, twice!!) if I have more catheter blockages! With this information in mind, is there any way that the process of allowing this Uroshield Device to be a prescribable item to be speeded up as I'm on emergency time before urosepsis creeps in again, and next time I might not make it. Help please?!! Many thanks [REDACTED]</p>	<p>technology but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.</p>
41	5	Patient	General	<p>Dear NICE,</p> <p>My thoughts on using the Uroshield on the trial have been very positive & reassuring, both physically and mentally. The reasons I mention this is because prior to using the Uroshield, I was having catheter blockages every other day & at major risk of contracting urosepsis, which unfortunately I did suffer with on two or three occasions. I couldn't even leave the house!! My anxiety was through the roof.. I was constantly wet, in severe pain, highly embarrassed & traumatised. I was placed in an undignified/humiliating situation greatly affecting the quality of my life.</p> <p>With the use of the Uroshield things are much more positive, much easier to manage & allows me to have much more freedom, i.e, I feel more back in control of my own life. A large degree of dignity is returning to my life, not to mention the considerable saving both to the nurses time & the large financial saving to the NHS.</p> <p>I'd like to thank everyone involved in this project for giving me this valuable opportunity to trial this product.</p> <p>Many thanks, Yours Sincerely [REDACTED]</p>	<p>Thank you for your comment.</p> <p>The committee values comments about the experiences of people who have used the technology. It carefully considered these comments along with the evidence and expert advice.</p>
42	7	Member of the public	General	<p>We have lived next door to [REDACTED] for over 35 years. During that time we have witnessed the increasing problems for</p>	<p>Thank you for your comment.</p>

				<p>the family brought on by the progressive development of [REDACTED] MS.</p> <p>These problems have been exacerbated by the issues caused by the necessary use of a catheter, namely catheter blockages and UTI's. This resulted on many occasions in an ambulance being called and [REDACTED] spending some time in hospital and then frequent home visits from the District Nurse.</p> <p>The effect both physically and mentally was traumatic for the family, and adversely affected their social life.</p> <p>Over the past three years [REDACTED] has been using UroShield, and the benefits have been noticeable. [REDACTED] suffered only one UTI in that period, thereby reducing the need for ambulances, A & E staff and District Nurses, all at a cost saving to the NHS. Equally however the significant mental benefit in being able to have an improved social life is immense.</p> <p>I would request NICE make UroShield available to all those who would benefit as [REDACTED] has done.</p>	<p>The committee values comments about the experiences of people who have used the technology. It carefully considered these comments along with the evidence and expert advice.</p> <p>Please see NICE's responses to comment 3.</p>
43	8	Health and social care professional	General	<p>I have worked in the care industry for many years and during that time have experienced dealing with catheterised clients suffering UTIs. In some cases, and particularly when finding a client extremely unwell on arrival at their early morning call, there has been no alternative but to call for an ambulance to admit the client to hospital for the necessary treatment and inpatient stay. The UroShield device appears to be a great step forward in preventing UTIs in the first place, thus removing the need for ambulance call outs, hospital stays, additional care calls on return home, etc. It seems this new device is very easy to wear and to use so I hope NICE will approve it and make it widely available as soon as possible</p>	<p>Thank you for your comment.</p> <p>The committee values comments from healthcare professionals about their experience using the technology.</p> <p>Please see NICE's response to comment 3.</p>
44	9	Member of the public	General	<p>My father in law has had the urosheild for some time and has benefited greatly. This has reduced the number of urinary tract infections hugely and in turn the number of hospital admissions. In turn this has saved him unnecessarily being distressed by hospital stays and immense savings to the nhs in such difficult times when their focus needs to be in other areas. Thank you immensely to the team who have enabled him to benefit from this amazing technology. We certainly hope that others can</p>	<p>Thank you for your comment.</p> <p>The committee values comments about the experiences of people who have used the technology. It carefully considered these comments along with the evidence and expert advice.</p>

				benefit too. This has been groundbreaking and we are thankfully.	If a technology is recommended for use in research, the recommendations are not intended to preclude the use of the technology but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.
45	11	Patient	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	<p>Thank you for asking me to comment on UroShield device.</p> <p>I have had a permanent suprapubic catheter over 8 years after my High Dose Radiotherapy (HDR) for Prostate Cancer. After a few months following insertion of the catheter, it began getting blocked and urinary flow became very feeble during the last 4 to 6 weeks prior to changing the catheter . As I have a Silicone catheter it needs to be changed every 3 months.</p> <p>I was advised to use “ Opti Flow Solution” to flush it out every week to “wash off “ biofilm which kept developing in the lumen of the catheter & tube and became opaque very quickly instead of being transparent.</p> <p>I had frequent blockages when I had to attend A & E to change catheter. During my Surgical Training, I had to deal with blocked catheters in patients on numerous occasions and I know what a stressful experience it is!</p> <p>When I had to attend A & E as a patient for blocked catheter, obviously I was very anxious with waiting in the A & E before being dealt with and suffered pain and bladder spasms due to inability to urinate. Now, due to the Covid Pandemic, the situation has become worse, and wait is much longer, and patient is NOT allowed to bring relative or companion which makes things worse when one is in pain.</p> <p>Luckily, in January 2019, my Urologist, [REDACTED] informed me about the UroShield device he read about in a report in the Urology Journal, where the device was recommended by Consultant Urologist, [REDACTED]. He suggested that I buy the UroShield device which I promptly did. And what a difference it has made to my life over the last 3 years - no more</p>	<p>Thank you for your comment.</p> <p>The committee values comments about the experiences of people who have used the technology. It carefully considered these comments along with the evidence and expert advice. It concluded that UroShield shows promise but there is currently not enough evidence to make a positive recommendation. The EAC noted that from a clinical perspective, the evidence is very limited and there are no patient groups identified other than short term versus long term catheterization. Further research is recommended to identify if specific patient groups may benefit from using UroShield.</p>

				<p>blocked catheter, pain or bladder spasm and I feel confident to travel freely all over UK and I have also been to Germany on a Medical Conference prior to the Covid Pandemic. Before using UroShield I very much stayed within easy reach of my Teaching Hospital where I trained and worked. UroShield has given me freedom and confidence and the support from I.M.S. has been fantastic.</p> <p>As a Medic and now as a patient I know UroShield is most useful invention for patients with long term catheters. I believe that if UroShield was to be made available on the NHS, it will save NHS considerable cost by eliminating unscheduled changes of catheters and cost of A & E attendances. It will improve patient's lifestyle- free them from infection, antibiotics, blockages, pain and bladder spasms.</p> <p>I wholeheartedly recommend UroShield should be available to all patients using long term catheters and I hope NICE will be able to recommend it for all long-term catheter users.</p> <p>Kind regards</p> <p></p> <p>Fellow Royal Society of Medicine</p>	
46	12	Member of the public	General	<p>My mother is the prime carer for my father who has secondary progressive MS and I know how much she is affected by my father's condition. It has governed her life, and his, for some 47 years but she makes the most of what they can still do. However, when my father becomes ill with an infection my mother has to go into full nursing mode (not something she trained for!) and has latterly often followed an ambulance taking my father to hospital suffering from a UTI. The impact on his MS when he has an infection is devastating and he requires 24 hour care at home from my mother when released from a stay in hospital. What a transformation in both my parents lives over the last 3 years now that my father uses UroShield. It shows what a huge impact this new device has, not only on those needing to use it but also on their carers or family or medical staff.</p>	<p>Thank you for your comment.</p> <p>The committee values comments about the experiences of people who have used the technology. It carefully considered these comments along with the evidence and expert advice. The potential benefit of UroShield in reducing the use of antibiotics was considered in the cost model and Section 4.1.</p> <p>Please also see NICE's response to comment 3.</p>

				Coming from a medical background myself, I am very strongly against the use of long term, prophylactic antibiotics. This is something that should be avoided at all costs to prevent antibiotic resistance and that is exactly what UroShield has achieved. As well as the massive improvement this device has made to my parents' life, I hope NICE will consider that antibiotics not being required on a regular basis is another huge benefit of using UroShield.	
47	13	Patient	General	<p>I have had a suprapubic catheter for around 20 years now and during that time have experienced more and more UTIs and catheter blockages. Also two episodes of septicaemia, one being directly associated with a catheter change. Weekly catheter washouts and also taking prophylactic antibiotics became a regular part of my life. However, since the autumn of 2018 I have been using UroShield which has transformed my life. I have suffered only one UTI in 3 years! Catheter blockages are a thing of the past. I am no longer spending days at a time as a hospital inpatient because of the impact of a UTI and was able to stop the antibiotics completely. I can get out and about, do so much more, not be worried about whether I will be well enough on a certain day to meet friends and family or attend appointments.</p> <p>UroShield is worn discreetly, and a huge plus is that it isn't intrusive or yet another drug to be taking. I have lost count of the number of District Nurses who on seeing the device wished they could have it for many of their patients, some of whom they see almost daily apparently to perform a wash out because of a catheter blockage.</p> <p>I appreciate that the company involved in producing this new technology has been working through the difficulties of Covid but the document seems to support so many of UroShield's attributes and hopefully NICE will wish to make it available on the NHS to all, and reap the many benefits of this unique device.</p>	<p>Thank you for your comment.</p> <p>The committee values comments about the experiences of people who have used the technology. It carefully considered these comments along with the evidence and expert advice. It concluded that UroShield shows promise but there is currently not enough evidence to make a positive recommendation. The EAC noted that from a clinical perspective, the evidence is very limited and there are no patient groups identified other than short term versus long term catheterization. Further research is recommended to identify if specific patient groups may benefit from using UroShield.</p>
48	14	Health and social care professional	General	This is an email that we received from a patient who underwent a trial of Uroshield. She came to the end of the 12 week trial and is now desperate to continue using it. Her GP has written to the CCG to fund it, but she has had no luck yet.	<p>Thank you for your comment.</p> <p>The committee values comments about the experiences of people who have used</p>

				<p>My thoughts on using the Uroshield on the trial have been very positive & reassuring, both physically and mentally. The reasons I mention this is because prior to using the Uroshield, I was having catheter blockages every other day & I couldn't even leave the house!!</p> <p>My anxiety was through the roof..</p> <p>I was constantly wet, highly embarrassed & traumatised.</p> <p>I was placed in an undignified/humiliating situation affecting the quality of my life.</p> <p>With the use of the Uroshield things are much more positive, much easier to manage & allows me to have much more freedom, i.e, I feel more back in control of my own life. A large degree of dignity is returning to my life, not to mention the considerable saving both to the nurses time & the large financial saving to the NHS.</p> <p>However I think some upgrades are needed for the convenience for the everyday user.</p> <p>These are as follows -</p> <ol style="list-style-type: none"> 1) Battery life needs extending to a whole day (12 hours +) for more convenience to the user. 2) A second rechargeable battery would be more convenient so when one goes flat, you can just change it over to another rechargeable battery therefore not interrupting your day or night. 3) The battery pack unit & actuator could be smaller/more discreet. 4) The unit display could have the charging status on it in the form of percentage level or time remaining indicator, together with a countdown timer when the actuator has to be changed. 5) For the discretion and the convenience for the user, a soft carry case would be useful with some form of strap to enable the user to attach it to their leg or ankle. <p>I'd like to thank everyone involved in this project for giving me this valuable opportunity to trial this product.</p>	<p>the technology. It carefully considered these comments along with the evidence and expert advice.</p>
49	14	Health and social care professional	General	<p>We have run a product evaluation on the Uroshield device in a group of neurological (mainly spinal cord injury SCI) patients with a supra-pubic catheter (SPC). The patients were identified</p>	<p>Thank you for your comment.</p>

				<p>in the SPC clinic as those who had experienced recurrent catheter blockages and who regularly had to attend A&E or have call outs to the district nurses to change their catheter when it became blocked. Blocked catheters in SCI patients can lead to autonomic dysreflexia which can become life threatening. Most of the patients who trialled the device found it beneficial. The main disadvantage was the battery length and charging. Although our cohort of patients is relatively small, we feel that the cost of the device would easily outweigh the costs of repeated A&E visits or district nurse callouts. We feel that these patients would greatly benefit from being able to access this device through their GP or on prescription</p>	<p>The committee values comments from healthcare professionals about their experience using the technology. It carefully considered these comments along with the evidence and expert advice.</p> <p>Please see NICE's response to comment 3.</p>
50	16	Health and social care professional	2.3	<p>I have observed less no of catheter blockage and recurrent urinary tract infections in patients following SCI which has improved their quality of life by reducing sepsis and hospital admissions.</p>	<p>Thank you for your comment.</p> <p>The committee values comments from healthcare professionals about their experience using the technology.</p>
51	18	Member of the public	General	<p>My 90 year old father is a long term suffer of MND and as such, he has been permanently catheterised for circa 6+ years. For the first few years he had very regular catheter blockages which resulted in attending A&E via ambulance. He also suffered many UTI's which oral antibiotics at home were unsuccessful in treating and this resulted in many hospital admissions, again all via ambulance.</p> <p>Routine catheter changes within the Urology Department at our local hospital are scheduled for every 12 weeks however he very rarely attended these appointments as the catheter was being changed far more frequently. We recall a minimum of 27 changes within one year, with three being in one day whilst in hospital.</p> <p>The trauma and pain that each UTI or blockage causes my father cannot be measured, but he becomes very poorly with the average stay in hospital being between seven and ten days. As my father is predominantly house bound and non-weight bearing, to actually move him whilst unwell is very uncomfortable and painful for him.</p>	<p>Thank you for your comment.</p> <p>The committee values comments about the experiences of people who have used the technology. It carefully considered these comments along with the evidence and expert advice.</p> <p>The cost model for UroShield accounts for reductions in costs of hospital admissions because of the reduced frequency of urinary tract infections (UTIs) and catheter-associated bloodstream infection (CABSI).</p> <p>Please also see NICE's response to comment 3.</p>

				<p>We were introduced to the Uroshield as a trial. The changes that this made to Dad is unbelievable. It cannot be a coincidence that UTI's and blockages ceased from that moment. The only catheter changes became the pre booked 12 weekly.</p> <p>In more recent times, Dad has had admissions into hospital with UTI's however these are thankfully very infrequent, and I must state that we are likely to have exceeded the 'life expectancy' of the device which may account for these incidences.</p> <p>I really am a firm believer that whilst the Uroshield is a very simple device, it is incredibly effective and efficient. It is not unreasonable to say that the Uroshiled is definitely a life changer I would also add, potentially a life saver. A cost comparison between the Uroshield and hospital admissions is not something thing that I am able to do however, I would imagine one attendance to A&E via ambulance is far more expensive than the device?</p> <p>I would be more than happy to further discuss the benefits that this has provided my father, and it must be said, the family also. I would be more than happy to provide more support or information if needed, either by telephone, e-mail or in person.</p> <p>Thank you.</p>	
Cost modelling (n=18)					
52	1	Member of the public	4.7	<p>It is perhaps worth noting that UroShield helps to realise the cost saving of this NHS practice to keep catheters for longer. Without UroShield catheter blockages which were not resolved by wash-out frequently forced an early catheter change, meaning that the new catheter and district nurse appointment to exchange it were required before the target six week duration. During the three years using UroShield the patient expert has had no further catheter blockages.</p>	<p>Thank you for your comment.</p> <p>The effect of UroShield on the costs of changing a catheter were included in the model. The committee understood that the technology is likely to be cost saving for patients with frequent blockages. However, there were uncertainties in the cost modelling because of the limited clinical evidence available.</p>

					Please see NICE's response to comment 3.
53	2	Patient	2.3	<p>in my personal case my catheters have a life expectancy of 4 weeks but in practice i went threw a period never reaching my planned changed date . i was regulary calling the district nurses to effect an unplanned cathertire change . this is dispite a constant vidual and a daily review of basic maintainence . cathertire massage and keeping the junctions clear of cediments and the occasional wash out .</p> <p>i am aware of the cost factor involved , cathertire plus nurse call out and time not to foget my own discomfort pain and angerish . all of the above in my mind must surely cover the cost of the divice .</p>	<p>Thank you for your comment.</p> <p>The committee values comments about the experiences of people who have used the technology. It carefully considered these comments along with the evidence and expert advice.</p> <p>The effect of UroShield on the costs of changing a catheter were included in the model.</p>
54	2	Patient	2.6	<p>in my personal opinion the cost is out weighed by the benefits gained .</p> <p>i would have thought it a cost effective option for the NHS in some circumstances .</p>	<p>Thank you for your comment.</p> <p>The committee values comments about the experiences of people who have used the technology. Modelling showed that UroShield would be cost saving if a patient in the community had more than 3 blockages per month (requiring a nurse visit and catheter change), or a catheter-associated UTI at least once every 5 months. However, there are uncertainties in the cost modelling because of the limited clinical evidence available.</p>
55	2	Patient	3.10	I would agree with this statement	Thank you for your comment.
56	2	Patient	3.10	<p>in my opinion the cost is outweighed by the benefits in materials and time relating to cathertire change and what should be taken into consideration is the discomfort pain and anxiety brought on by cathertire issues such as blockages .</p> <p>then there is the mental health aspect to be considered in dealing with UTI and verious medical conditions .</p>	<p>Thank you for your comment.</p> <p>The committee values comments about the experiences of people who have used the technology. It carefully considered these comments along with the evidence and expert advice.</p>
57	2	Patient	3.15	i refer to my comments with regard to the effects on each individual . this can be evidanced by the local community teams	<p>Thank you for your comment.</p> <p>The committee values comments about the experiences of people who have used</p>

					the technology. It carefully considered these comments along with the evidence and expert advice.
58	2	Patient	3.16	i agree	Thank you for your comment.
59	6	Member of the public	3.10	the costing seems to be general population, however the costing for those patients with chronic CAUTI, are repeatedly admitted to hospital, taking regular antibiotics, having frequent blockages and catheter changes, the costs associated with their care would be increased, so the genuine savings cant currently be measured against a general population.	Thank you for your comment. Cost modelling was done for 6 populations in hospital or community settings. This included people in the community with recurrent catheter-associated UTI. Modelling showed that (at the base rate of effectiveness) UroShield would be cost saving if a person in the community had more than 3 blockages per month, or a catheter-associated UTI at least once every 5 months.
60	6	Member of the public	3.16	this has a huge impact especially with such a stretched work force - either no hospital admissions, or reduction of community nursing team visits.	Thank you for your comment. The cost savings of reduced hospital admissions and nursing time were both considered in the EAC's cost models.
61	10	Health and social care professional	2.6	These costs will be less than that of ambulance transport, A+E care +/- a hospital admission on a regular basis for a UTI or blocked catheter.	Thank you for your comment. Cost modelling showed UroShield would be cost saving in hospital settings and in people in the community with more than 3 blockages per month, or a catheter-associated UTI at least once every 5 months. However, there are uncertainties in the cost modelling because of the limited clinical evidence available.
62	10	Health and social care professional	3.16	Here uroshield is likely to have a significant impact from what I have observed and saved cost wise in our selected patient population.	Thank you for your comment. The committee values comments from healthcare professionals about their experience using the technology.
63	15	Company	3.11	We agree with the findings on cost-effectiveness highlighted by the EAC.	Thank you for your comment.

64	15	Company	3.13	We agree with the findings on cost-effectiveness highlighted by the EAC.	Thank you for your comment.
65	15	Company	3.14	We agree with the findings on cost-effectiveness highlighted by the EAC with regard to community patients with recurring UTI and specific hospital patients. We welcome the opportunity to study the effects of UroShield with patients at risk in the ICU.	Thank you for your comment.
66	15	Company	3.16	We appreciate the additional analysis performed by the EAC which focussed on the benefits of UroShield in preventing catheter blockages independent of CAUTI. UroShield was found to be cost saving for people who do not get catheter-associated UTI but who have 3 or more blockages that require a catheter change. Clinicians have fed back to us that we should highlight this UroShield benefit as there are many patients who do not suffer with CAUTI but who have many catheter blockages. Encrustation of the catheter is a common occurrence causing recurrent blockage in 40-50% of long-term catheterised patients (Getliffe).	Thank you for your comment. Section 4.5 has been amended to highlight the potential cost savings associated with a reduction in blockages. The committee considered that UroShield showed promise in reducing blockages, but more evidence is needed.
67	15	Company	4.11	Patient and clinician testimonials for patients using UroShield support the economic case for the device and we believe that the cost savings may be understated. Gage et al (2017) reported that "unplanned catheter related events occur regularly with 43% of participants in the study accessing out of hours services and 15% accessing A&E over the 12-month study period. Moreover, one third of DN visits were outside of routine scheduled care and some hospitalisations may be avoidable. Catheter-related problems cause distress for patients, reduce quality of life, and create unplanned expenditure for the health service. Exploring ways to reduce adverse effects of catheter use would result in significant patient benefit and health service savings and is a priority". The patient population most at risk of CAUTI often have complex underlying health conditions and treatment required can therefore be significantly more expensive as they require specialist transport and care. Clinicians have stated that UroShield contributes to keeping at risk patients out of hospital	Thank you for your comment. The community cost model provided by the company was based on the risks and costs included in CG139. The results were based on an approximately 75% reduction in the need to treat catheter-associated UTI, including nurse visits and hospital admissions for catheter-associated bloodstream infection. Please also see NICE's response to comment 61.

				and is proving to be a valuable device for this patient population, especially in light of the ongoing Covid 19 pandemic.	
68	15	Company	4.12	UroShield has a high percentage of success in preventing catheter associated UTI's and preventing blockages, pain and discomfort suffered by long term catheter users.	Thank you for your comment.
69	17	Healthcare researcher	3.9, 4.1, 4.2	A blocked catheter in the community is a medical emergency which requires immediate attention from the community nursing service and the catheters of several patients on our study have been reportedly blocking up to twice a week in some cases prior to the study. This is disruptive and costly for the nursing service and effects their ability to deliver routine care efficiently to other patients.	Thank you for your comment. The committee values comments from healthcare professionals and researchers about the experiences of people who have used the technology. It carefully considered these comments along with the evidence and expert advice. Please see NICE's response to comment 61.
Further research (n=5)					
70	15	Company	4.13	The company will continue to conduct research into the benefits of UroShield, particularly in more specific care settings and powered to capture both primary and secondary outcomes. An issue that presents itself is the fact that a high percentage of patients in the treatment group, along with their carers and clinicians, notice a difference, usually within days. The blockages, pain and spasm decrease, and the patients report that they feel better. This will contrast significantly with patients and their carers in the sham group who will know very quickly that they have an inactive device as the catheter continues to block, they have no reduction in pain and spasm and the patient will not feel any better than before the sham device was applied. This indicates that an RCT may not be the best design as the sham group will not be motivated to continue the study.	Thank you for your comment. The committee carefully considered the research needed to address the current gaps in the evidence. It recognised the potential challenges of doing an RCT but concluded that this would be the most robust and efficient design to confirm the promising results of the existing studies. The final guidance proposes in the Further Research section randomisation not just at the individual level but also at the group level as well as well-designed before and after studies.
71	15	Company	4.5	Demonstrating a reduction in CAUTI has been the priority in historic studies, however, patients and clinicians continue to report that within days of using UroShield, the urine clears, debris is seen in the collection bag (the crystalline deposits of the bacteria) and blockages cease.	Thank you for your comment.

				We agree with the clinical experts that more evidence would be beneficial regarding the positive effect that the device has on reducing or eliminating catheter blockage. We encourage the committee to discuss this with the Southampton study team as they have been collecting data on bacterial invasion of catheters and blockage and believe that laboratory examination of these catheters will add valuable evidence on the effect of UroShield on blockages.	
72	17	Healthcare researcher	3.5	We are mid-way through a research study evaluating the NanoVibronix Uroshield device and, although data collection is not yet complete and analysis has barely begun, we believe it may be helpful to share some of our initial observations to add to your evidence of the efficacy and usefulness of this device. Unfortunately, by the time this study is completed and published your consultation period will be over. This study is funded by BBSRC/Innovate National Biofilms Innovation Centre and NanoVibronix and is conducted independently of any company involvement, by the University of Southampton. We are recruiting 30 volunteers who live in the community and have been identified by the community nursing service as experiencing frequent infection or blockage with their long-term catheters. The aim of the study is to observe the effect of the device on the microbiota in the urine and on the catheter as well as the impact on the individual. It is not designed as a comparative study.	Thank you for your comment. The committee valued the additional information provided on the ongoing study by the University of Southampton. It considered that while this study may provide additional evidence on patient experiences and the effect of UroShield on the microbiota in the urine, it will not resolve the uncertainties in effectiveness given the study's aims and design.
73	17	Healthcare researcher	3.6, 4.2	Microbiological analysis of samples is underway but has not been completed. Initial observations also confirm a reduction in debris within the urine and some reduction in bacterial numbers. When completed, results will determine effects on bacterial numbers in urine and development of biofilm on the catheters, and using next generation sequencing will determine any effects on the community structure and species found.	Thank you for your comment. Please see NICE's response to comment 72.
74	17	Healthcare researcher	3.9, 4.1, 4.2	Our observations of the 12 participants who have so far used the Uroshield and participated in a recorded one-to-one interview show that some have attributed life-changing benefit to the device. Nearly all have reported a noticeable reduction in the amount of debris and encrustation seen in the catheter after	Thank you for your comment. Please see NICE's response to comment 72.

				around a week of use and several have reported fewer blockages which require an unscheduled catheter change. Our sample consists almost exclusively of wheelchair users who lead active lives but nonetheless rely on carers for some of their everyday needs, so catheter leakage as a result of blockage can lead to far-reaching consequences for their well-being. A leaking catheter leads to wet skin, clothing and bedding and often a lengthy wait for assistance. This has a profound effect on the dignity of the individual, as well as their skin health and their plans for the day.	
Consultation question responses (n=16)					
<i>Has all of the relevant evidence been taken into account?</i>					
75	6	Member of the public	Consultation question	yes all evidence has been reviewed	Thank you for your comment.
76	10	Health and social care professional	Consultation question	Yes	Thank you for your comment.
77	14	Health and social care professional	Consultation question	I think the evidence that is available has probably been taken into account. It is very difficult to run large scale randomised controlled trials in this sort of patient group	Thank you for your comment. Please see NICE's response to comment 70.
78	15	Company	Consultation question	Further Developments since the submission The Southampton Study which was delayed due to the pandemic has been progressing since April 2021 and is due to conclude, early in 2022. We believe that interim data from this study is available which will strengthen the evidence base for patients with long term catheters who are at high risk of CAUTI and blockages. We encourage the committee to consider evidence from the Southampton study team . A further CCG (Northamptonshire) has engaged to discuss use of UroShield for high risk patients . NHS Supply Chain have started a market engagement activity with potential providers on a operating model to supply UroShield to patients. Additional NHS Trusts have commenced patients with UroShield and clinicians from these Trusts may respond to the recommendations directly.	Thank you for your comment. Please see NICE's response to comment 72. The committee valued the additional information provided by the company. If a technology is recommended for use in research, the recommendations are not intended to preclude the use of the technology but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.
<i>Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?</i>					

79	6	Member of the public	Consultation question	yes but only considers cost of the general population not specified population which will benefit from this.	Thank you for your comment. Please see NICE's response to comment 59.
80	10	Health and social care professional	Consultation question	Yes	Thank you for your comment.
81	14	Health and social care professional	Consultation question	I think there is reasonable interpretation of the evidence. In our patient cohort (neurogenic patients with long term catheters, community based) I think the clinical and cost effectiveness may be greater than short term, hospital based users. I feel that although they may be a relatively small group of patients, they should not be denied the opportunity of benefiting from this device because of this	Thank you for your comment. Please see NICE's response to comment 59.
82	15	Company	Consultation question	We agree that the evidence for the benefit of UroShield in people with short-term catheters is limited and cannot be used to definitively support any clinical benefit at this time. However, the evidence for patients with long term indwelling catheters who are community based is much stronger and suggests that the use of UroShield for this specific patient group will reduce UTI, catheter-related complaints and improve quality of life.	Thank you for your comment. Please see NICE's response to comment 3.
<i>Are the recommendations sound and a suitable basis for guidance to the NHS?</i>					
83	6	Member of the public	Consultation question	The recommendations are for general board population, this will have the better impact on a small significant population, that can be clearly defined to control cost and give the stranger cost effectiveness.	Thank you for your comment. Please see NICE's response to comment 3.
84	10	Health and social care professional	Consultation question	I agree that more research is needed though evidence so far from both patients and the studies have shown the device to be safe, to reduce CAUTI in at risk patients and exhibit a cost saving to the NHS in those patients. There is further benefit to both the patient and the NHS in using Uroshield for patients with catheter blockages not associated with UTI as mentioned in the da Silva study and the case reports.	Thank you for your comment.
85	14	Health and social care professional	Consultation question	Please take into account that neurogenic patients with long term catheters are a small group, but are probably disproportionately	Thank you for your comment.

				affected by CAUTI and blockages, and anything that can improve quality of life should be available	Please see NICE's response to comment 3.
86	15	Company	Consultation question	<p>The evidence base is strongest in the community population of people with long term indwelling catheters and this is supported by the evidence synthesis. It is known that duration of catheterisation is a key risk factor for CAUTI and this would be one of the primary criteria in identifying high risk patients who would benefit most from UroShield. It is expected that most patients in the community who have need of long-term indwelling catheterisation will need it for their lifetimes. The clinical experts, the committee and the patients and clinicians all agreed that recurrent UTI's can have a devastating impact on a person's quality of life. It considered that preventing catheter-associated UTIs and other catheter-related problems is a significant unmet need, especially in people with long-term catheters in the community and people with recurrent UTIs would be highly motivated to use UroShield.</p> <p>We encourage the committee to make UroShield available to existing users who would be devastated if the device was not available to them and specific patients in community settings identified by clinicians, with high risk of CAUTI.</p>	<p>Thank you for your comment.</p> <p>The committee has carefully considered the evidence and the input from the patient and clinical experts. It concluded that UroShield shows promise but there is currently not enough evidence to make a positive recommendation.</p> <p>If a technology is recommended for use in research, the recommendations are not intended to preclude the use of the technology but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.</p>
<i>Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?</i>					
87	6	Member of the public	Consultation question	No	Thank you for your comment.
88	10	Health and social care professional	Consultation question	No	Thank you for your comment.
89	14	Health and social care professional	Consultation question	<p>Patients with a neurogenic disability associated with SCI or MS often require long term catheterisation. They are often affected by CAUTI and blockages. It would be a shame to discriminate against them due to lack of current evidence as doing RCTs in this group is quite difficult due to patient numbers. The personal comments from some of our users has been very positive.</p>	<p>Thank you for your comment.</p> <p>The committee has carefully considered the evidence and the input from the patient and clinical experts. It concluded that UroShield shows promise but there is currently not enough evidence to make a positive recommendation. The EAC noted that from a clinical perspective, the evidence is very limited and there are no patient groups identified other than short term versus long term catheterization. Further research is recommended to</p>

					<p>identify if specific patient groups may benefit from using UroShield.</p> <p>If a technology is recommended for use in research, the recommendations are not intended to preclude the use of the technology but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.</p> <p>The final guidance proposes in the Further Research section randomisation not just at the individual level but also at the group level as well as well-designed before and after studies.</p>
90	15	Company	Consultation question	<p>Many of the existing users of UroShield are elderly and also suffer with a number of comorbidities such as arthritis, asthma, chronic anxiety, depression, diabetes, heart disease, neurological conditions, sleep disorders and dementia. They are also one of the patient populations at greatest risk of coronavirus. Through the continued use of UroShield, these existing patients experience a reduction or elimination of infections and blockages, reduced use of antibiotics and therefore, less dependency on NHS staff and resources. We believe that unless there is a recommendation for these patients to receive UroShield through the NHS, it will potentially result in them not having access to the device, resulting in an adverse impact on their lives.</p>	<p>Thank you for your comment.</p> <p>Please see NICE's response to comment 89.</p>

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."