

# Innovative Medical Technology Overview: Number 010/2018

This IMTO summarises the evidence relating to a technology submitted for assessment by the manufacturer. This IMTO offers an impartial review of the strengths and weaknesses of the technology to contribute to local decision-making by NHS health professionals, managers and procurement colleagues. IMTOs do not make recommendations and should be considered alongside existing guidance applicable to NHSScotland.

## Homechoice Claria® with Sharesource®



## Summary

Homechoice Claria® with Sharesource® is an automated peritoneal dialysis (APD) system. Homechoice Claria® is an APD cyclor which performs dialysis overnight while the patient sleeps. The technology under review is the addition of Sharesource® to the existing Homechoice® device. The combined unit uploads all treatment information to a secure cloud-based platform (Sharesource®) where healthcare professionals (HCPs) can access it and monitor patient treatment. It is a two-way platform that gives HCPs remote visibility of a patient's treatment outcomes such as fill volume, dwell time and total therapy time. Any issues are highlighted using a flag system, and these flags can be customised according to the individual renal unit's protocols. The system allows the HCPs to change the devices' default settings such as alarms and prescription parameters.

The data from Sharesource® is transmitted from a modem within the APD cyclor. Only a weak mobile telephone signal is required. At clinics, access to the Sharesource® portal requires a computer and the internet.

## Product performance

The manufacturer's submission is based upon 16 poster presentations. Eight posters described various clinics' experience of Sharesource®; four were case studies; two described how Sharesource® could be used to review treatment; and two detailed an economic model that was also published as a full paper.

Together, the posters suggest that the technology may facilitate an increased uptake of APD. They also suggest that compared to APD without remote monitoring, Sharesource® allows the earlier identification of any issues with treatment, enabling intervention before problems escalate. Some posters report that the remote technology enables nurses' time to be spent on more proactive tasks. In addition, some report that Sharesource® allows home visits to be targeted at those most in need.

The high level detail given in the posters means that a thorough assessment of robustness is not possible. It is possible that the evidence presented in the posters is over-stating the benefits of Sharesource®. However, early results are promising and further research is encouraged.

## Economic considerations

The manufacturer states that Homechoice Claria® with Sharesource® is provided at the same cost as an APD cyclor without the Sharesource® component.

The manufacturer highlighted a published economic analysis which aimed to assess the potential impact of the technology on use of healthcare resources and costs in the United States, Germany and Italy. The analyses were based on 12 APD patient profiles. Total savings were estimated to be \$1,947 per case in the United States, \$957 per case in Germany, and \$590 per case in Italy.

Economic analyses are available which suggest that peritoneal dialysis is a cost effective dialysis option. However, further research would be required to establish whether Sharesource® increases uptake of APD. No evidence is available that allows conclusions to be drawn on the potential resource implications of Sharesource® for NHSScotland.

## Safety

The manufacturer argues that Sharesource® makes APD safer, because HCPs can monitor treatment and respond to any abnormalities before they escalate. However, they also caution that patients still need to be taught about their responsibility to report issues or concerns that they have with their treatment, particularly if they feel unwell.

No specific safety data were provided with the submission.

## Organisational and patient issues

With Sharesource<sup>®</sup>, specialist nurses would monitor their patients' treatment daily, anticipate treatment problems, make changes remotely, and target home visits to those most in need. This daily monitoring, including responding to any 'red flags', is likely to increase workload. However, this may be offset by time savings in other areas (one example highlighted by a peer reviewer was talking patients through the process of reprogramming machines over the phone).

Sharesource<sup>®</sup> is a cloud-based technology and requires that a 'data privacy agreement' is signed by the manufacturer and the participating hospital. This can be a time consuming process, and an NHSScotland-wide data privacy agreement may be a more suitable alternative.

The evidence provided did not explore patient issues in detail. However, APD is associated with improvements in certain dimensions of quality of life.

## Overview of technology

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Baxter launched their new automated peritoneal dialysis (APD) system in 2015 – Homechoice Claria® with Sharesource®. This technology enables remote patient management (RPM) of patients having APD at home. Homechoice Claria® with Sharesource® is a class 2b device.

Homechoice Claria® with Sharesource® is intended for use in people with end stage renal failure (ESRF). ESRF is when chronic kidney disease (CKD) has progressed so far that renal replacement therapy (regular dialysis treatment or kidney transplantation) is required to maintain life. Kidney transplantation is not suitable for all people receiving dialysis.

Homechoice Claria® is an APD cyclor which performs treatment overnight while the patient sleeps. The technology under review is the addition of Sharesource® to the existing Homechoice® device. The combined unit uploads all treatment information to a secure cloud-based platform (Sharesource®) where healthcare professionals can access it and monitor patient treatment. Sharesource® is a two-way platform; settings and device programme information can be managed remotely and summary reports can be generated. Sharesource® is embedded within the Homechoice Claria® cyclor.

The Sharesource® dashboard shows clinicians which patients have received dialysis, whether there were any issues and the nature of the issues. It also shows how patients' prescriptions compare to their delivered dialysis dose. The two-way connectivity allows clinicians to change the devices' default settings such as alarms, prescription parameters such as fill volume, dwell time and total therapy time. Problems are highlighted using a flag system, and these flags can be customised according to the individual unit's protocols<sup>1</sup>.

Only authorised users are able to remotely view information from the Sharesource® platform, and manage treatment. All hospitals using the technology have a signed data-sharing agreement with Baxter. The patient also has to agree to the Sharesource® patient consent in order to use the Sharesource® feature of the machine. If patients do not give this consent, the APD cyclor can still be used, but their treatment data will not be uploaded to the Sharesource® platform.

The manufacturer states that Sharesource® is the only two-way remote management system available for dialysis patients who treat themselves at home. A high level search conducted by Healthcare Improvement Scotland did not highlight any other similar technologies. Some studies on the use of telemedicine in patients with kidney disease were identified, but these generally involved phones (for calls or texts), videoconferencing, or applications/software on tablet computers.

## Comparator(s) and use in pathway of care

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In Scotland, on 31 December 2016 there were 5,026 patients receiving renal replacement therapy (RRT). Of these, 57% of patients had a functioning kidney transplant, 37% were being treated with haemodialysis (HD) and 4% with peritoneal dialysis (PD)<sup>2</sup>. The topic referrer states that 30-35% of people requiring dialysis could be treated with PD, although clinical experts advise that this may be an overestimate.

The main factors that determine the choice of dialysis type, HD or PD, are patient preference to suit their lifestyle, individual clinical factors and the local availability of treatment within a service. PD is done at home. HD can be done either at home, in hospital or at a satellite dialysis centre. Patients who have HD at renal clinics have to travel three times per week for their treatment<sup>3</sup>.

For patients being treated with APD at home, the alternative to Homechoice Claria<sup>®</sup> with Sharesource<sup>®</sup> would be a conventional APD cyclor *without* remote two-way patient monitoring and management.

NICE guidelines recommend that all people with stage 5 CKD are offered a choice of PD or HD if appropriate<sup>4</sup>. NICE guidelines also state that PD should be considered as the first choice of treatment modality for:

- Children two years old or younger
- People with residual renal function
- Adults without significant associated comorbidities

The manufacturer proposes that Homechoice Claria<sup>®</sup> with Sharesource<sup>®</sup> may facilitate the increased uptake of PD. The proposed advantages of home-based PD, compared to HD at renal clinics, are 'improved patient well-being, greater relaxation, a higher quality of life and improved survivability rates'<sup>5</sup>. However, the manufacturer states that uptake of home-based PD has been difficult to achieve in the past. They suggest this is likely due to a number of factors, such as lack of nurse resource and lack of confidence among patients that they are being adequately monitored. The manufacturer also notes challenges with treatment adherence. PD without remote patient monitoring requires patients to maintain logs of their treatment, which can lead to delays in identifying issues as concerns need to be raised by telephone calls between the clinic and the patient. Changes to prescriptions are often made following clinic consultations. The impact of that change will typically not be reviewed until the next appointment, which may be months later<sup>1</sup>.

The manufacturer states there are currently approximately 9,400 patients worldwide using APD with Sharesource<sup>®</sup>. In Scotland, 55 people are using the Homechoice Claria<sup>®</sup> with Sharesource<sup>®</sup> (figures true for March 2018): Ayrshire & Arran (9 patients); Edinburgh Royal Infirmary (12 patients); Fife (5 patients); Glasgow Western (25 patients); Yorkhill (4 patients).

## Product performance

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There are no peer-reviewed published data directly comparing APD with Sharesource® to APD without Sharesource®. Sharesource® is an emerging technology, and it should be recognised that the evidence base is still being developed.

### Evidence submitted by manufacturer

The manufacturers included 16 poster presentations with their submission (two of these are described under the economic considerations section). It should be noted that posters give only high level details; full critical appraisal was not possible.

Seven of these posters described changes that were observed after the implementation of Sharesource®:

### *Resource use*

- Pharro and Lewis (2017)<sup>6</sup>: The authors collected 12 months of data following implementation of Sharesource® at one hospital in Southend. They reported that 218 remote programme treatment changes were made in the 12 month period, and also that:
  - The number of PD patients increased from 21 to 32;
  - The number of home visits dropped from 24 (out of 24 PD patients 3 months after implementation) to 10 (out of 32 PD patients) at the end of the year.The authors concluded that implementation of the Sharesource® system had enabled healthcare professionals to predict problems and act with timely intervention, and to target home visits to those most in need. As a result, they were able to grow their PD numbers with no additional nurse resource.
- Chukwu et al (2017)<sup>7</sup>: This study compared two equal sized cohorts of patients before and 6 months after the implementation of Sharesource® at Aintree University Hospital. The authors reported that in the cohort who had PD with Sharesource®, there were fewer cases of PD peritonitis (eight versus five); fewer PD-related admissions (eleven versus nine); and fewer hospital attendance spells (55 versus 45).
- Patterson et al (2017)<sup>8</sup>: This study from Gloucester Royal Hospital compared audit data from 12 months prior to the implementation of RPM using Homechoice Claria® with Sharesource®, and 12 months after. The outcomes reported included a decrease in the number of incoming patient phone calls (32 per month versus 14.7 per month on average); a 21% increase in proactive care; and a 4% reduction in reactive care. The authors concluded that utilising the Homechoice Claria® with Sharesource®, coupled with a dedicated PD team and a regular home visit protocol, 'enabled the development of an increased, sustainable PD programme that provides timely and efficient patient centred care'<sup>8</sup>.

### *Prescription changes*

- Firanek et al (2017a)<sup>9</sup>: This study evaluated the number of monthly individual prescription changes in the 6 month period after the introduction of APD cyclers embedded with a two-way remote patient management platform. Data were used from 544 USA patients (using Baxter's Automated PD System) and 189 patients from Europe, Asia and Latin America (using Homechoice Claria<sup>®</sup> with Sharesource<sup>®</sup>). The authors concluded that remote PD prescription changes peaked after one month of the technology being introduced, and then declined over the following 5 months, stabilising at 6 months.

### *Patient opinions and nurse care*

- Wilson et al (2017)<sup>10</sup>: This study consisted of telephone interviews with 13 APD patients before and after the implementation of Homechoice Claria<sup>®</sup> with Sharesource<sup>®</sup>. Following the introduction of RPM, the patients were asked how safe and confident they felt undertaking their dialysis at home where 1=not at all confident to 10=completely confident; the mean rating was 9.8. Furthermore, prior to the introduction of RPM the majority of patients attended for routine nephrology outpatient clinics once every 2 months, with the mean duration of the visit being 58 minutes. Following the introduction of remote management, the majority of patient's reported attending every 3 months, and the average duration of the clinic visit was 34 minutes.
- Firanek et al (2017b)<sup>11</sup>: This UK study aimed to examine whether the introduction of RPM technology changed how nurses used their time, and whether more time was spent on activities that were ranked as 'higher-value' by nurses and patients. It involved online surveys with 25 nurses, and telephone surveys with patients (number not given), in order to rank eight interactive tasks, considering the value of each task in helping patients feel more confident and safe when using PD. It then involved four PD nurses, from different hospitals, being observed on one day before the implementation of RPM technology, and one day afterwards. The authors reported that following implementation of RPM, nurses spent more time on the four activities rated as 'higher-value'.
- Firanek et al (2017c)<sup>12</sup>: This study compared nurses' behaviour and practice in the care of patients on APD at home. Three nurses, from different hospitals, were observed before and after implementation of Sharesource<sup>®</sup>. The authors reported that establishing remote patient management allowed nurses to spend 35% more of the patient activity time conducting proactive tasks (tasks initiated by the nurse in order to intervene regarding an issue before it is reported by a patient).

### *Additional information*

A number of additional posters described individual cases (Drepper et al 2017<sup>13</sup> García et al 2017<sup>14</sup>; Puig et al 2017<sup>15</sup>; Gómez et al 2017a<sup>16</sup>; Gómez et al 2017b<sup>17</sup>; Firanek et al, 2017d<sup>18</sup>). Benefits of RPM were reported to be as follows:

- Early identification of problems
- Improved compliance with treatment
- High patient satisfaction

- Usefulness of Sharesource® to review patterns of ultrafiltration by APD cycle, and analyse factors influencing it.

Finally, one poster described early experiences of using Sharesource® in children (Great Ormond Street Hospital for Children) in the UK (Blaauw 2017<sup>19</sup>). The author listed the benefits they had experienced including: the ability to make proactive PD treatment changes remotely; enhanced patient confidence in home dialysis; identification of early catheter problems; identification of potential retraining issues; and improved communication between the PD team and parents of children having PD at home.

### Literature search

The evidence submitted by the manufacturer was supplemented with a high-level literature search conducted by Healthcare Improvement Scotland. This highlighted a systematic review<sup>20</sup> and two non-comparative studies on remote monitoring of patients having dialysis at home, but not specifically on Homechoice Claria® with Sharesource®<sup>21, 22</sup>. In addition, two poster abstracts were identified that had not been included in the manufacturer submission<sup>23, 24</sup>.

The systematic review (He *et al*, 2017) included eight trials that evaluated the effects of remote home management of patients with CKD<sup>20</sup>. None of the studies included Homechoice Claria® with Sharesource® as the intervention, or something similar. However, the review highlights some advantages of remote management in CKD and so has been included here for information. In five studies, remote monitoring was done via the telephone, either in the form of a call or text message. In the remaining three studies, care was provided via television or videoconferencing. The authors of the review reported that compared to typical care, remote home management improved certain dimensions of quality of life; and also resulted in decreased hospital readmissions, emergency room visits and number of days in hospital. The authors noted that people tended to comply with remote home management, regardless of their gender, age or nationality. However, the effects on blood pressure and cost effectiveness were not clear from the studies included. The included studies were small with potential biases, and the authors highlighted the need for good quality trials in this area.

Two non-comparative studies evaluated RPM of patients using computer tablets<sup>21, 22</sup>. In both studies, patients were required to enter details daily into applications/software on tablets, which in turn could be monitored by medical teams. The authors of both studies reported favourable results. Dey *et al* (2016) included 22 patients, and concluded that ‘satisfaction scores and retention rates suggest a high level of acceptability’ and that ‘further avenues in developing such technologies should be explored in renal patients’<sup>21</sup>. Harrington *et al* (2014) included six patients (undertaking continuous ambulatory PD, rather than automated PD), and concluded that a tablet computer platform ‘may encourage more patients to take up PD as their preferred modality for end-stage renal disease’<sup>22</sup>.

The search also highlighted two additional poster abstracts not included in the manufacturer submission:

- Firanek *et al* (2015) evaluated healthcare professionals’ and patients’ perceptions of an APD cycler with RPM. The authors reported that advantages were identified in terms of



‘usability and data management’, and they concluded that the technology ‘may make PD more deliverable from the point of view of both patients and HCPs’<sup>23</sup>.

- Zevenbergen *et al* (2018) described an American clinic’s experience of converting 33 PD patients to an APD cyclor (Amia®) with the Sharesource® platform. The authors listed benefits for the staff, patients and facility and concluded that ‘the daily treatment data can be overwhelming, but the overall benefits allow better outcomes/treatments for our patients and better utilization of staff time’<sup>24</sup>.

### Ongoing studies

The manufacturers advise that there are currently ten studies in progress with approximately 12 further studies planned across 14 countries. This includes clinical evaluations of Sharesource® currently being conducted at Great Ormond Street Hospital, London and Southend Hospital, Essex. A multi-site audit is also being conducted in three NHS England hospitals.

## Safety

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In the manufacturer’s submission they suggest that Sharesource® makes APD safer as clinicians can monitor treatment and respond to any abnormalities before they escalate. However, they caution that patients still need to be taught about their responsibility to report issues or concerns they may have with their treatment, particularly if they feel unwell.

No other safety data were provided in the submission.

## Strengths and limitations of the evidence

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Homechoice Claria® with Sharesource® is a new technology, and as such the evidence base is in its infancy and still evolving.

The product performance evidence provided by the manufacturer consisted of poster presentations. The level of detail provided in posters is insufficient to allow for critical appraisal. Therefore, the methods employed and the results presented cannot be properly assessed for robustness. Furthermore, the numbers of patients included in the studies were generally small.

However, the early data are promising and it is plausible that this technology could be of benefit to patients and represent good value for money.

## Economic considerations

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The manufacturers state that Homechoice Claria® with Sharesource® is provided at the same cost as an APD cyclor without the Sharesource® component.

The manufacturer submission included a study published as a full paper and two posters<sup>25-27</sup>. The posters report on the same analyses<sup>25, 27</sup>.

The study by Makhija *et al* (2018)<sup>26</sup> aimed to estimate the potential impact of remote treatment monitoring on APD patients' use of healthcare resources and costs in the United States, Germany and Italy. The analyses were based on 12 APD patient profiles (with and without RPM). Two versions of each profile were created to simulate healthcare resource use, one assuming the use of RPM (using Sharesource®) and one without. Eleven APD teams estimated the resources that would be used. Estimated reduced utilisation across the three countries ranged from one to two hospitalisations, one to four home visits, two to five emergency room visits, and four to eight unplanned clinic visits. Total savings across all scenarios were estimated to be \$23,364 (\$1,947 per case) in the United States, \$11,477 (approximately \$957 or €872 per case) in Germany, \$7,088 (approximately \$590 or €538 per case) in Italy. No sensitivity analyses were reported.

The manufacturer states that there are currently two clinical evaluations of Homechoice Claria® with Sharesource® being conducted in the UK at the Great Ormond Street Hospital in London and at Southend University Hospital in Essex. These will include an economic evaluation to assess the impact of adopting the technology.

Although there is no evidence which assesses the cost effectiveness of Homechoice Claria® with Sharesource® in NHSScotland, there are some economic analyses which suggest that PD is a cost-effective dialysis option. For example, an economic analysis from 2014, from a UK taxpayer perspective, concluded that 'increasing PD use among incident dialysis patients would be cost-effective, associated with reduced costs and potential modest improvements in quality of life'<sup>28</sup>. Similarly, a Norwegian systematic review and health economic decision model concluded that 'PD was the most cost-effective dialysis alternative and was comparable to HD regarding efficacy outcomes... there are significant saving potentials if more end-stage renal patients are started on PD instead of HD'<sup>29</sup>. Therefore, if it can be demonstrated that Homechoice Claria® with Sharesource® increases uptake of APD – and that this in turn leads to lower healthcare resource use - then it is feasible that the technology would be cost-effective. Further analyses are encouraged, to allow more definitive conclusions to be drawn.

## Organisational and patient issues

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Specialist nurses based in a renal unit are often responsible for leading and managing the care of patients using PD<sup>1</sup>. Patients receiving PD have to attend outpatient clinics (the manufacturer states that this is typically every 3 months). Without RPM, patients are required to keep paper records of their dialysis, and bring them to the clinic for review. With RPM, clinicians would be able to: see records in advance of scheduled clinics (freeing up time to spend discussing other aspects of patient care); continually monitor treatment, making changes remotely; anticipate treatment problems, allowing proactive interventions; target home visits to those most in need.

Sharesource<sup>®</sup> is a cloud-based technology; consideration needs to be given to cyber security and data protection. The manufacturer states that data transferred between devices is encrypted, and strong passwords are required by all users. Data back-ups are also encrypted. In order to implement this technology a 'Data Privacy Agreement' needs to be signed by Baxter and the participating hospital. The manufacturer states that this is a time consuming process, and is a barrier to the uptake of the Sharesource<sup>®</sup> technology. A peer reviewer also noted this as a potential barrier. The manufacturers propose a possible alternative could be to apply an NHSScotland-wide data privacy agreement, negating the need for separate paperwork for each hospital.

The data from Sharesource<sup>®</sup> is transmitted from a modem within the APD cyclor. Only a weak mobile telephone signal is required, though this may not be available for some people. At clinics, access to the Sharesource<sup>®</sup> portal requires a computer and the internet.

The benefit of APD to patients is that it is associated with improved quality of life due to patients being able to have treatment at home, rather than travelling to hospital three times a week. The additional proposed patient benefit of the Sharesource<sup>®</sup> technology is that it provides patients with confidence that their treatment is being monitored, allowing early identification and rectification of potential problems.

One charity (Kidney Research UK) was invited to peer review this IMTO. They submitted comments from two patients, one of whom had experience of APD. Neither had experience of Sharesource<sup>®</sup>. Both respondents were positive about the technology, but highlighted the importance of patients still being able to contact HCPs in case of any concerns.

## Conclusions

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The evidence surrounding the use of telemedicine in people receiving dialysis at home is sparse, although the limited number of studies undertaken report promising results. The authors of a good quality review from 2017 (He *et al*, 2017<sup>20</sup>) highlighted the need for more research in this area.

Regarding Homechoice Claria® with Sharesource®, the evidence base is in its infancy and still evolving, and definite conclusions are not yet possible. However, the technology appears to offer advantages over other telemedicine methods; for example, treatment information is uploaded automatically, and clinicians can make adjustments to treatment schedules remotely. The manufacturers suggest that this may provide reassurance to patients that they are being adequately monitored, and therefore has potential to encourage more patients (for whom it is appropriate) to have PD at home. The manufacturers also argue that healthcare professionals may also be more inclined to encourage PD if they are able to have better oversight of daily treatment parameters, including treatment adherence. This could result in improvements in quality of life for patients, and potentially cost savings for NHSScotland. However, the reasons for low uptake of PD are complex, and it is not yet clear the extent to which Sharesource® would encourage uptake of APD. Further research is encouraged, in particular around the economic and resource impact of Homechoice Claria® with Sharesource®.

### **What is an IMTO?**

Innovative Medical Technology Overviews (IMTOs) summarise the evidence relating to an individual technology that has been submitted by the manufacturer of the technology.

The purpose of IMTOs is to provide information that will contribute to local decision-making by NHS health professionals, NHS managers, and procurement colleagues.

IMTOs do not contain recommendations for NHSScotland and should be considered alongside existing guidance applicable to NHSScotland.

**Chair**

**Scottish Health Technologies Group**

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