

manufactured safely in Germany but are not yet available in the U.S. There are companies working to bring EP ablation catheters to the U.S. (these are considered Class III) but none have come to market yet.

OEMs most always have a negative response to re-manufacturing because it threatens their business. It is important that re-manufactured SUDs be subjected to regulation that is equivalent to that of the OEM. As an industry, we want regulation because it helps to assure the credibility of our industry and provides legitimacy. OEMs point to potential safety concerns and, while these are important, the industry has been operating safely for 20 years. When looking at safety, it is also very important to look at regulated re-manufacturing vs. in-hospital reprocessing. Regulated re-manufacturing is safe. On the other hand, in-hospital reprocessing is prone to problems and difficult oversight challenges. Most countries choose to regulate re-manufacturing while simultaneously disallowing or setting high standards that prevent in-hospital reprocessing.

In Europe, there are only 2-3 re-manufacturers. In a heavily regulated environment, this is natural because few companies can meet the high standards that have been set. Vanguard is the largest company in Europe and you will meet with them tomorrow. Vanguard was built from the ground up as a re-manufacturer. In addition to re-manufacturing, they also re-sterilize reusable devices as well.

In Canada, it used to be that re-manufacturing was regulated at the province level, but this has changed and now it is regulated at the national level. As a service, regulation at the local level makes more sense because local authorities are assessing factories and processes. As a product, this doesn't make sense and it is more reasonable to regulate through a centralized body.

Every country seems to be developing their own standards but the FDA has led the way. In the future, I think there will be a harmonization effort. Given what your group is doing, I think your work and the results could be a very important part of regulatory harmonization.

1. Germany has regulated remanufacturing since 2002
2. Germany's KRINKO requirement doesn't distinguish between "multiple" use and "single-use" devices and doesn't place restrictions on what products can be re-manufactured. Instead, it requires that the re-manufacturers prove that their process is safe for the product that is being re-manufactured.
3. Germany has chosen to regulate reprocessing as a service rather than as a product/sale.
4. In Europe, there are only 2-3 re-manufacturers. In a heavily regulated environment, this is natural because few companies can meet the high standards that have been set.

Dr. Katrin Westphal
German Federal Ministry of Health
February 9, 2016
2 p.m. – 3p.m.

In Germany the practice of reprocessing Medical Devices has been regulated since 2000. We are expecting that the EU will release their guidance for medical device remanufacturing by July of this year. This will be an overarching guidance for all of Europe; each country will be able to opt in or out when it comes to remanufacturing.

Legally there are two different ways in which these reprocessed devices are classified. One is for the higher risk device where the reprocessed device gets a CE marked and can be along side other CE marked devices. And the other is a “service” where a reprocessor is providing a service to hospitals by cleaning and reprocessing the devices for repeated use. Germany does not regulate remanufacturing of devices, we regulate reprocessing of medical devices and we make no distinction between Single use devices (SUD), and Multiple use devices (MUD).

All reprocessing will have to adhere to Recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) from the Robert Koch Institute (RKI). This is a standard that has been created for safe hospital standards regarding infection control/management. KRINKO includes guidance for reprocessing of medical devices as well as other HAI management guidance.

The ordinances (Medical Device act), which are the EU directives, are going to require that devices be placed on the market according to an approach that will treat the remanufacturer the same as an OEM, which means that they will have to obtain CE markings for products, do clinical investigation that validate the cleaning, sterilization, and remanufacture process. All responsible persons involved will have to be registered. And notified bodies will have to approve the device. Currently there are three notified bodies that can handle reprocessed devices. When a device is remanufactured, the intended use, design of the device must be documented, with no change from the OEM. Also information relating to Post market surveillance is documented as well.

The remanufacturer has to follow rules in order to remanufacture as well. They will have a responsibility to have a validated and documented remanufacture procedure, which includes cleaning, sterilization, the remanufacture of the device, and the packaging. Also the OEMs instructions must be respected as well, so this means that the intended use, and use of the device must not change. Also the functionality following remanufacturing must be guaranteed and verified.

We also require information on performance testing, and safety testing. The testing data is kept at the manufacturer, we are interested in the testing results, it is not required that the process and the whole entire process validation be shared with us.

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However all manufacturers can be audited to see if they are operating in a proper manner.

If there is an incident where a device is involved the operator will have to notify (us) the German ministry of health, and then we will step in and work with the manufacturer if necessary to see what the exact reason for the incident was. There are times when the incident has no relation to the manufacture or the product, and it is at the fault of the operator

In Germany we need to have the reprocessor adhere to the Medical Devices act and KRINKO. For manufacturers that do not conform to the Medical Devices act, they can be imprisoned for up to three years. Also if a device that can create greater risk and harm to a patient is released, the manufacturer could face imprisonment as well.

As I mentioned before we do not differentiate between SUD and MUD for reprocessing, because the OEM manufacturer is free to label the device as a SUD without proving why it is a SUD. So instead the reprocessor is required to prove that a device can be reprocessed/remanufactured safely. When a reprocessor of a device wishes to put a product on the market for sale they are required to obtain a CE mark.

There are two structures that reprocessed devices have to follow in Germany. One is at the operational level; this is the Koch Institute, KRINKO guidance for caregivers as well as reprocessors. And the others will be the notified bodies that will ultimately rule on the CE marking.

The EU will release guidance later this year and will treat all remanufacturers as OEM manufacturers. It will be up to the individual country to remanufacture or not, in Germany we have been very confident with our process and the way that we manage this industry so we are still discussing with them how to transition into the new guidance.

Marc Thanheiser, Applied Infection Control & Hospital Hygiene
Robert Koch Institut
February 9, 2016
2 p.m. – 3p.m.

KRINKO is the Commission for Hospital Hygiene and Infection Prevention, this is an official mandate that was made to create guidance on the control and prevention of hospital acquired infections (HAI). The aim of the guidance is to control / decrease infection rates and to prevent any breakout of diseases. This is primarily for the care facilities (operator), but also for reprocessors.

We have set standards and limitations on hospital protocols that have an impact on HAI prevention/risk. Specific to the reprocessing of medical devices is the “Hygiene Requirements for the Reprocessing of Medical Devices.” This is a section of KRINKO deals how to properly handle and reprocess medical devices. There is no differentiation between a SUD and a MUD, all devices if they are reprocessed must follow the KRINKO regulations.

KRINKO does not require the hospital/manufacture to make any type of submission or create documents that need to be sent to us. Instead we have audits in place to see if hospitals and manufacturers have the proper systems in place to adhere to guidance.

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 2. All reprocessing will have to adhere to Recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) from the Robert Koch Institute (RKI). This is a standard that has been created for safe hospital standards regarding infection control/management.
 3. The ordinances (Medical Device act), which are the EU directives, are going to require that devices be placed on the market according to an approach that will treat the remanufacturer the same as an OEM, which means that they will have to obtain CE markings for products, do clinical investigation that validate the cleaning, sterilization, and remanufacture process.
 4. We do not differentiate between SUD and MUD for reprocessing, because the OEM manufacturer is free to label the device as a SUD without proving why it is a SUD. So instead the reprocessor is required to prove that a device can be reprocessed/remanufactured safely. When a reprocessor of a device wishes to put a product on the market for sale they are required to obtain a CE mark.
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MHRA Meeting

February 11, 2016

9:30 a.m. – 11:30 a.m.

London

We have been studying re-manufacturing and are about to release our guidance document. A draft has been prepared and the final version is being reviewed with our solicitors. It should be released in June or July. The final document will be very similar to the draft with only a few modifications.

The re-use of SUDs is currently prohibited in the UK and levels of re-use are minimal. However, we recognize that there is a lot of waste because of the prevalence of single-use devices. In the 1980s, it made sense to shift to SUDs out of fear of infection; however, this resulted in manufacturers over producing SUDs. They are incentivized to do this because it increases their sales. It also reduces the burden for them because they don't have to prove that the device can be re-used and also don't have to develop cleaning and disinfection protocols. It is a win-win for manufacturers but has fueled an increase in healthcare costs and the reality is that we all know many devices can be re-used safely if proper procedures are used.

We differentiate between in-hospital "reprocessing" and "re-manufacturing." Our policy is that reprocessing should not be allowed; however, re-manufacturing should be allowed because the processes used are more rigorous – including cleaning as well as significant testing. We feel confident in re-manufactured SUDs but the re-manufacturer needs to make a submission to a notified body and obtain a CE mark. Provided they can do this, we are very willing to accept re-manufactured devices.

We have chosen not to have a prescriptive approach and have left it to the manufacturer to prove their case to the notified body. Because their manufacturing process is different, they need to outline their own process which includes cleaning as well as the testing that I referenced before. They also face different risks because their products are re-used. Because of this, they also need to identify these risks and provide a full risk assessment as part of their submission. If they can do these and the products are CE marked, we accept them. We do not restrict the products that can be re-manufactured and don't have specific additional requirements. They do need to meet the OEM standard and go through the same process. We do not allow them to just say that they are the same as the OEM so they should be able to sell or be subjected to lower requirements.

Currently, the only products planned for the market are Class II products. Class III isn't prohibited but manufacturers have decided not to submit them for approval. This could be due to a variety of factors: inability to re-manufacture safely, economics that don't support the re-manufacturing and sale of the products, or the manufacturer's decision not to take on the risk associated with re-manufacturing these devices.

When developing their technical files / dossiers, re-manufacturers are at a disadvantage because they aren't the OEM. They have two potential sources of information regarding the OEM devices that they use. In some countries (such as the US), they can get redacted versions of the OEM submission. This is

very helpful. If they can't get this or if the file doesn't contain enough information, they have to rely on reengineering to fill in the missing bit. Reengineering is an important part of the process when re-manufacturers develop their submission. It is a tool that helps them provide the information required in the dossier. We don't really care what the reengineering process is or regulate it. We only care about the results. If, like the OEM, they can provide the information needed for to get a CE mark, then that is all we really care about.

With respect to the possible risks associated with changes in the OEM device, this needs to be considered as part of the re-manufacturer's quality system. Re-manufacturers need to continuously inspect OEM devices to make sure there aren't significant changes. They can also look for press releases, customer feedback, etc. but direct inspection is essential and they need to include information about this process in their technical file.

As I mentioned, we do not allow reprocessing in the UK. Our guidance will also indicate that we do not allow re-manufacturing of Class I devices. These devices are very safe but our own process for evaluating them is very vague and, at this stage, we don't think it is appropriate for a re-manufactured product to be marketed unless it has undergone some sort of approval. This may change in the future but, for now, these devices don't reflect a significant opportunity and aren't as important. We also don't have a process for reviewing these devices so we aren't comfortable allowing them to be re-manufactured. The FDA allows re-manufacturing of SUDs and has a much more rigorous process. If you'd like to introduce re-manufactured Class I devices, I suggest looking at the FDA model.

One important consideration with re-manufactured devices is that it is critical that there be rigorous tracking. Without tracking, the re-manufacturer won't know how the device has been used or whether or not it has been re-manufactured or reprocessed elsewhere. Each device will need to have to be uniquely identified with a barcode and tracked. If a device isn't in the re-manufacturer's system, then it needs to be disposed of. The re-manufacturer has submitted for approval based on its own process and it is not able to validate other processes. Tracking and a closed loop in which specific devices are only re-manufactured by a single company are critical. If a hospital wants to use re-manufactured devices, it needs to either contract with a single company or have a process in place that ensures a device is only ever re-manufactured by a single company.

We don't regulate this but re-manufacturers also enter into contracts with their customers to help manage risk and to create an extra safety net. The re-manufacturer must track and inspect but, in practice, they also contractually obligate the hospital to do things that help to ensure safety. For example, they may set restrictions on product handling, prevent hospitals from submitting devices that have been exposed to patients with specific infections, etc. It is always possible that the hospital will make a mistake so the re-manufacturers processes need to allow for this but creating contractual obligations with the hospital can reduce risk and reduce the likelihood of damage to a product (making it more likely that it can be re-manufactured).

In terms of facilities, we don't require any special certifications for the re-manufacturer. They need to meet the same standards as an OEM or any other manufacturer in the jurisdiction that governs their manufacturing facility.

In addition to the tracking described above, the re-manufacturer also needs to relabel the product. The label needs to include the unique identifier as well as the name of both the OEM and the re-manufacturer. The re-manufactured device is the full responsibility of the re-manufacturer but the clinician needs to know the name of the original device.

We have been involved in discussions to develop the EU standard. A guidance document will be published by the EU in June or July (subject to some delay) and it will be very similar to the guidance that is being released in the UK. The guidance will outlaw reprocessing and allow for the sale of re-manufactured with a CE mark. The key difference will be that countries will have the ability to opt out. This is primarily because of Germany which would like to opt out and continue to allow reprocessing by hospitals. France will also opt out and not allow re-manufacturing. Our understanding is that this is because of internal politics and, perhaps, lobbying by the OEMs. There may be a few other countries that opt out but, on the whole, most of Europe will follow the EU guidance. With respect to reprocessing, there will be a three year grace period to implement the changes.

We do not require informed consent and this will not be required as part of the EU guidance. The reason for this is that devices only receive a CE mark if they are safe and have the same intended use. Since the devices are the same and there is no elevated risk to the patient, it isn't appropriate to require informed consent. This is the same in the US.

With respect to reimbursement, we have a DRG-like system. It is possible that at some point in the future, the DRG rates will be re-calculated to reflect the lower cost associated with re-manufacturing; however, for now, we expect the savings to benefit the hospital and to enable them to use the savings in other areas. As you know, the UK is under extreme cost pressure. Patients will benefit from the cost saving through additional resources – money spent on extra staff, other devices, etc. They may also benefit from lower taxes over the long run. For now, our opinion is that they don't need to benefit directly from the lower cost of the re-manufactured device. They aren't exposed to higher risk and we don't make adjustments based on price differences between OEM devices either.

The cost savings can be quite significant. We expect to see 30-50% savings for re-manufactured devices. Initially, the amount will be lower because of high transport costs but we expect this to change once the devices are re-manufactured in-country. It is also important to consider waste reduction. The amount of medical waste produced by SUDs is incredible. Re-manufacturing is entirely logical, safe, and is a good way to reduce waste as well.

The OEMs definitely put up resistance. Negative messages are always stronger than positive messages. Most of their arguments are quickly debunked. They are very quick to confuse in-hospital reprocessing with re-manufacturing. There are some terrible examples of problems with in-hospital reprocessing – this is why it is not allowed but we do not know of any examples of adverse events attribute to re-manufacturing. In fact, there is evidence that re-manufactured devices have fewer problems. This is because every item is tested by a re-manufacturer while OEMs only batch test.

In our own studies, the primary benefits of re-manufacturing are savings and waste reduction. On the negative side, there is a slightly higher burden to the hospital because they have to help with sorting. It can also be difficult to get physician buy-in in the beginning because the perception is that re-use is bad. However, from the experience in the US and Germany, it is clear that these obstacles can be overcome.

It really is the obligation of the OEM to do more to make products re-usable. They need to be engineering devices that can be re-manufactured or re-used easily. In fact, in the future, maybe we need to consider requiring the OEM to explain why they have chosen to make the device single use.

1. We have been studying re-manufacturing and are about to release our guidance document. A draft has been prepared and the final version is being reviewed with our solicitors. It should be released in June or July.
2. We differentiate between in-hospital “reprocessing” and “re-manufacturing.” Our policy is that reprocessing should not be allowed; however, re-manufacturing should be allowed because the processes used are more rigorous – including cleaning as well as significant testing.
3. When developing their technical files / dossiers, re-manufacturers are at a disadvantage because they aren’t the OEM. They have two potential sources of information regarding the OEM devices that they use. In some countries (such as the US), they can get redacted versions of the OEM submission. This is very helpful. If they can’t get this or if the file doesn’t contain enough information, they have to rely on reengineering to fill in the missing bit. Reengineering is an important part of the process when re-manufacturers develop their submission.
4. As I mentioned, we do not allow reprocessing in the UK. Our guidance will also indicate that we do not allow re-manufacturing of Class I devices. These devices are very safe but our own process for evaluating them is very vague and, at this stage, we don’t think it is appropriate for a re-manufactured product to be marketed unless it has undergone some sort of approval. This may change in the future but, for now, these devices don’t reflect a significant opportunity and aren’t as important.
5. One important consideration with re-manufactured devices is that it is critical that there be rigorous tracking. Without tracking, the re-manufacturer won’t know how the device has been used or whether or not it has been re-manufactured or reprocessed elsewhere. Each device will need to have to be uniquely identified with a barcode and tracked. If a device isn’t in the re-manufacturer’s system, then it needs to be disposed of.
6. If a hospital wants to use re-manufactured devices, it needs to either contract with a single company or have a process in place that ensures a device is only ever re-manufactured by a single company.
7. In terms of facilities, we don’t require any special certifications for the re-manufacturer. They need to meet the same standards as an OEM or any other manufacturer in the jurisdiction that governs their manufacturing facility.
8. We have been involved in discussions to develop the EU standard. A guidance document will be published by the EU in June or July (subject to some delay) and it will be very similar to the guidance that is being released in the UK. The guidance will outlaw reprocessing and allow for the sale of re-manufactured with a CE mark. The key difference will be that countries will have the ability to opt out. This is primarily because of Germany which would like to opt out and continue to allow reprocessing by hospitals. France will also opt out and not allow re-manufacturing. Our understanding is that this is because of internal politics and, perhaps, lobbying by the OEMs. There may be a few other countries that opt out but, on the whole, most

of Europe will follow the EU guidance. With respect to reprocessing, there will be a three year grace period to implement the changes.

9. We do not require informed consent and this will not be required as part of the EU guidance. The reason for this is that devices only receive a CE mark if they are safe and have the same intended use. Since the devices are the same and there is no elevated risk to the patient, it isn't appropriate to require informed consent. This is the same in the US.
10. With respect to reimbursement, we have a DRG-like system. It is possible that at some point in the future, the DRG rates will be re-calculated to reflect the lower cost associated with re-manufacturing; however, for now, we expect the savings to benefit the hospital and to enable them to use the savings in other areas.
11. The cost savings can be quite significant. We expect to see 30-50% savings for re-manufactured devices. Initially, the amount will be lower because of high transport costs but we expect this to change once the devices are re-manufactured in-country. It is also important to consider waste reduction. The amount of medical waste produced by SUDs is incredible.

Ms. Vicky Griffiths, Cardiac Physiology Service Manager
Royal Brompton Hospital
February 11, 2016
1 p.m. – 2 p.m.
London

We are a public NHS hospital but we do some private practice as well. This is a specialized center that does large volumes cardiovascular procedures. We are one of the top institutions in the UK and we have all of the latest equipment. Manufacturers also like to work with us to trial new products and procedures. We are the only hospital in the UK with Stereotaxis.

We are a very busy center and we do not have any plans to expand so we are currently running more hours/days than before to compensate. I suspect that we will continue to be busier. Because we are in central London, there just isn't much room to expand. We are also under tight budgetary pressures and can't make the capital equipment investments needed to expand the facility. One of the reasons we are expanding is to take on more private patients. A doctor will typically handle up to 14 cases in a day.

We don't currently use re-manufactured devices and laws are quite strict so we don't do in-hospital reprocessing of any kind. As you know re-manufacturing hasn't been approved yet in the UK but MHRA is going to approve the devices – we are told there will be some within the next few months. Right now, we do participate in collections with Stryker and we are the first hospital in the UK to do this.

Once re-manufactured devices are approved, I'm not sure that we will adopt them quickly. The biggest challenge is that we are large and already have very strong buying power and tight relationships with the OEMs. We have obligations to our OEM suppliers and have pre-existing contracts with them. Also, I do not think that re-manufacturing will give us much buying power initially because Stryker does not yet have an entire family of products... only one product here and there. I think that we will suffer if, for example, we buy just the catheters from Stryker and the cables from the OEM. Also, if we are not able to fulfill the minimums for our sales agreement we may not get favorable pricing from the OEM. Another challenge is that we don't have funds for much of the capital equipment that we use. Some manufacturers provide the capital equipment because we then use their disposables. If we start to use re-manufactured disposables, I fear they would try to charge us for the equipment which we can't afford. Royal Brompton is also quite special. We are such an important center that OEMs will do anything to keep our business. It wouldn't be out of the question that they would just drop their prices to match Stryker so that we have no incentive to use them.

On the contrary, I think that smaller hospitals will be a good target for re-manufacturing and they will be far more receptive to the idea. I do not think that their relationships with the OEMs are as strong as ours so they will benefit more

from the cost savings. For smaller hospitals, re-manufacturing would be a good way to get leverage and better pricing.

I think that the only real way to get into the larger hospitals is to offer a broader range of products and whole product families. Pricing will also need to be very competitive. Head doctors may also be difficult to convert because they have to keep in mind their relationship with OEM suppliers. It will take time. I think that a good model for us is to start with collections and then bring on re-manufacturing at a later date. Unwinding existing OEM supply agreements alone will take quite a bit of time.

OEM relationships are not perfect. We have a failure rate of maybe 3 products a month and some of the devices do not even pass our initial visual inspection. I have also had a case where there was a hair inside of the sterile pack. In my opinion, OEM quality has dropped significantly. As you may know, they only batch test their products. A plus with re-manufacturers is that they test every product. There is evidence that they actually have lower failure rates than the OEMs.

Historically, recycling and disposing of medical devices has been a real source of stress for our hospital and staff. We used to clip the catheters ourselves to recycle the metal. This was a problem because it is fairly easy to cut yourself in the process and there is a risk of infection. It was also just a hassle. With Stryker, it is much easier for us. Now the nurses bring the catheters into this room, clean them as instructed and then pop them into a bag and then into the bin that has been provided. Stryker comes in each week to collect the catheters so our staff does not have to worry about it. Prior to this we had to worry about getting the catheters out of the hospital but now everything has become much simpler. I would suspect that we are putting about 50 catheters a week into the bins. Stryker pays us for the catheters and gives us full value for the precious metals. This is money that we can re-direct into other areas. It also reduces our waste disposal costs.

I am not worried about a re-manufactured product being less superior or having higher risk than an OEM device. It is all about the certifications/quality and, if a product is CE marked and approved for use, this is all that really matters to us. If we did use re-manufactured devices, we would not require informed consent. If the produce is CE marked, there would be no reason to require informed consent. Informed consent is for products that are investigational or have higher risk. The CE marking would indicate that re-manufactured products are the same. We at this hospital used to reprocess a lot. Now all we do is send the cables to a sterilization company.

If we were to use re-manufactured devices, it also isn't like we would use them on public patients and new devices for private patients. If the product is CE marked, then it is equivalent. Although savings wouldn't be passed along to the patient directly, it would go to the patient indirectly because the savings associated with re-manufacturing would help fund other services that provide benefit and, in the long run, it would help to keep taxes down.

The majority of our device purchase is upfront. Consignment is only for things that are not too commonly used.

1. We are a public NHS hospital but we do some private practice as well. This is a specialized center that does large volumes cardiovascular procedures. We are one of the top institutions in the UK and we have all of the latest equipment
2. We are also under tight budgetary pressures and can't make the capital equipment investments needed to expand the facility.
3. We don't currently use re-manufactured devices and laws are quite strict so we don't do in-hospital reprocessing of any kind. As you know re-manufacturing hasn't been approved yet in the UK but MHRA is going to approve the devices – we are told there will be some within the next few months. Right now, we do participate in collections with Stryker and we are the first hospital in the UK to do this.
4. Once re-manufactured devices are approved, I'm not sure that we will adopt them quickly. The biggest challenge is that we are large and already have very strong buying power and tight relationships with the OEMs.
5. I think that smaller hospitals will be a good target for re-manufacturing and they will be far more receptive to the idea. I do not think that their relationships with the OEMs are as strong as ours so they will benefit more from the cost savings.
6. I think that the only real way to get into the larger hospitals is to offer a broader range of products and whole product families. Pricing will also need to be very competitive. Head doctors may also be difficult to convert because they have to keep in mind their relationship with OEM suppliers.
7. OEM relationships are not perfect. We have a failure rate of maybe 3 products a month and some of the devices do not even pass our initial visual inspection. I have also had a case where there was a hair inside of the sterile pack. In my opinion, OEM quality has dropped significantly. As you may know, they only batch test their products. A plus with re-manufacturers is that they test every product. There is evidence that they actually have lower failure rates than the OEMs.
8. Recycling and disposing of medical devices has been a real source of stress for our hospital and staff. We used to clip the catheters ourselves to recycle the metal. This was a problem because it is fairly easy to cut yourself in the process and there is a risk of infection. It was also just a hassle. With Stryker, it is much easier for us. Now the nurses bring the catheters into this room, clean them as instructed and then pop them into a bag and then into the bin that has been provided. Stryker comes in each week to collect the catheters so our staff does not have to worry about it.
9. I am not worried about a re-manufactured product being less superior or having higher risk than an OEM device. It is all about the certifications/quality

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欧州 1 — 5 St. George's Hospital

Dr. Alex Grimster, Lead Invasive Cardiac Physiologist
St. George's Hospital
February 11, 2016
3 p.m. – 4p.m.
London

Our hospital does about 900 ablation procedures per year, and for each procedure we use an average of 3 catheters. This is a large hospital that is running at near capacity, but we do not have any plans to expand the grounds, instead we are increasing hours of operations as well as days.

Currently we are involved in the collections with Stryker, they take away all of our used catheters. At the moment we are not using remanufactured devices. I do not think that there will be any obstacles for remanufacturing, as I understand it we are waiting for the CE mark for the remanufactured products which we expect to be in July so we will start to use Stryker remanufactured products then.

In the UK the reuse of EP catheters has been stopped for about 18 years. Prior to this, reusing a catheter 5 times was not uncommon in fact it was normal. We used to gas sterilize and that was it, we did not have separate sterilization techniques unique to different materials. When the Bovine spongiform encephalopathy (BSE) epidemic happened ep catheter reuse had stopped. Another largely influential factor was AIDS/Hepatitis C in the 1980s. Recently we have not had any epidemics so the era is different. BSE was focused in England, more than a million cattle were slaughtered and about a hundred people died. In the late 90s we expected this to become a very large and serious epidemic, in the end it was much smaller than we thought but it did end reuse of medical devices.

In that has passed since then catheter technology has moved on as well. Today catheters have kill switches in them so the devices cannot be reprocessed and used multiple times. The fact that there are companies that can get around this and truly remanufacture a device to its original state is very attractive to us.

Another change has been an increase in the number cases that we handle per year. In 1996 we used to only do about 100 ablation cases per year, so it was a highly specialized procedure. Because we were doing a small number of procedures the cost to the NHS was very small as well. Now the number is far higher, I would say a ten-fold increase in 20 years. And the cost of the devices has inflated as well, which makes the procedure cost to the NHS far higher.

In the United States the Ablation catheter is a higher risk classification so the FDA does not allow the remanufacture of it that is why Stryker is not doing it. We would like them to remanufacture it though. The real benefit in remanufacturing is the cost savings, EP

catheters, mapping catheters; all of these are all very attractive to us. For example HALO is so expensive we typically do not use them here at this hospital, but may be remanufacturing will give us the opportunity to use this in the future.

As far as the effect this will have on our supplier and OEM relationships, I think this will change a bit. The prices are based on commitment and buying levels so this does remain a question. It is a reality that when Stryker gets the CE mark in the EU and can sell in England we are going to juggle all of our relationships. This will certainly change the market. The OEM will have to come up with new deals for us. As we begin to integrate Stryker products I suspect we will get less free things from the OEMs and they will sponsor less research. But that's what happens when prices go down, and new products emerge.

I do not think informed consent is needed for this situation and I will not require it. Informed consent is used to tell a patient about risk. Using a remanufactured device does not change the risk profile at all.

I don't think the cost savings from the remanufactured device needs to be passed down to the patient; also the reimbursement of these devices will not be any different from an OEM. Our hospital is funded by taxes, so if we save money on EP catheters the money will be redistributed. In the long run it may slow down the rate in which taxes may go up.

When the adoption of remanufactured devices happens, our doctors will not have a choice and will have to use the remanufactured devices. There is no greater risk and they are essentially the same thing as the OEM.

If I was to draw a line, and I had to, just to create a rule. I would say that the younger patients would get the new catheters. There is a need to buy new ones as well; also we will need to buy new catheters as well, not just old ones. This rule is arbitrary but I feel that it is better to have a rule so the doctor does not have discretion. Otherwise the doctor will do as he/she pleases.

We have looked at other solutions to the problem of reuse / and cost containment. One thing I considered was to re use the same catheter for the same patient. But this did not happen because the laws prohibited us from doing this.

What we are talking about here is a solution to cut down waste and treat more patients with same amount of money. In hindsight throwing everything away back in the 1990s seems so wasteful to me. I think remanufacturing will be successful in the UK, healthcare is centralized and here in the UK the institutions will be compelled to do this just simply based on the savings alone.

My (our) job is to deliver a very high level of healthcare at a very set budget, so

remanufacturing will take off. I think that the big hospitals will adopt this first and then the smaller hospitals will follow.

Currently we re-sterilize cables for electrophysiology, but nothing that enters the blood stream or that is not made of metal.

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欧州 1 — 6 Department of Health

Linden Watts

Department of Health

February 12, 2016

9:00 a.m. – 10:30 a.m.

London

My division is responsible for analyzing our major cost saving initiatives. Re-manufacturing of SUDs is one of these and I've been studying it for 6 months to assess the potential impact.

SUDs are a major cost driver for the healthcare system and have been since the 1980s. They are an easy choice for doctors but, as they have grown, they have become a very expensive choice for the healthcare system.

See accompanying presentation

The EU and UK guidelines are going to be very similar and both will come out at about the same time. The EU guidelines need to be respected by all countries but each country, including the UK, also has its own system and may be more restrictive.

Germany has decided to opt out of reprocessing restrictions. France has decided not to allow remanufacturing. The U.K. has decided not to allow remanufacturing of Class I devices. Regardless, once CE marked, a device can be sold anywhere in Europe. I think that, even in France, you will see that hospitals begin to use re-manufactured devices. It will be hard to keep them out.

The MHRA has decided not to allow Class I devices because we don't have good controls for these and they don't feel comfortable allowing re-manufacturing with a paper-only process. Class I devices are also very cheap so there is very little savings potential. We have excluded these from our analysis but you may wish to consider Pulse Oxymeters which are very high volume. I believe that in the US, Class I devices represent about 40% of the re-manufacturing market. Our estimates are smaller than they will be for Japan. You are a larger market and you may get more savings because of higher prices or local production.

The EU process was interesting and the OEM's under the auspices of EUCOMED put up a strong fight. They spread a lot of misinformation and this ultimately discredited them. They try to scare people by presenting papers and examples based on in-hospital reprocessing which is very different. In the end, the Medical Device Directive will be modified to allow re-manufacturing and to restrict reprocessing.

Neither the UK or EU will require informed consent. If the products are CE marked, there is no reason to require this because they are proven to be the same or equivalent. The evidence we have collected actually indicates that in many cases failure rates for re-manufactured devices are lower because the re-manufacturers have to test every device. I've included a link to a study on this in the electronic presentation file.

OEMs are expected to try to limit the success of remanufacturing. It is interesting that J&J has a re-manufacturing business but they actually use this to trap the customer and undermine remanufacturing. They will sell their own products through both channels but intentionally provide bad service on re-manufactured devices. They also work to reduce the yields on remanufactured devices so that the hospital doesn't save as much as they thought they would. We have also heard stories of OEM reps handing out pamphlets with misinformation, etc. We know there will be challenges but we have decided to support remanufacturing and to initiate education programs targeting care givers and major associations. I think this is critical to actually generate savings. In addition to direct savings, we expect re-manufacturing to result in competition against the OEM that causes them to reduce prices. The ultimate level of savings will also depend on competition among re-manufacturers. Stryker is the only company that has expressed an interest in the UK. If it is just them, they may not be willing to discount enough but they will never have a monopoly because they compete with the OEM.

Overall, the savings from re-manufacturing may be small but it is an important step and also helps to reduce waste and improve safety. It may be small but it is easy to implement and the US and Germany have been doing this for a very long time. The savings will also depend on supply. Savings will be higher if there is local manufacturing. It will also be higher if there is ample supply. To maximize savings, we are hoping to actually gain access to used French devices. If we rely solely on local product, there will be supply constraints. This will be very helpful to us. We are happy to benefit from the French decision.

I believe the French decided not to accept re-manufacturing because of a mix of physician skepticism and OEM lobbying. I don't know for sure. You might as Stryker or one of the other manufacturers.

In addition to remanufacturing, the other key initiatives for us are:

- standardization of best practice in key therapeutic areas. We think this will be the most important and have the greatest impact
- collective purchasing of gloves and other products on behalf of the NHS. We think we will save £ 500MN over 5 years via a new trial program
- improvements to the NHS Supply Chain program. This is our centralized portal for procurement that allows even smaller hospitals to access better prices

We are also beginning to look at the use of internet based monitoring and other eHealth solutions. If you have information on this, we would love to learn from your experience.

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