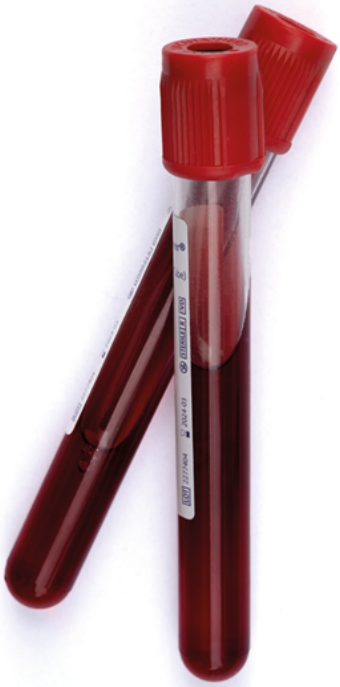

Recycling Blood Collection Tubes – a Feasibility Study

Summary of results

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Executive Summary

This summary report describes the effort and outcome of a feasibility study aimed at evaluating the possibility of recycling PET material from blood collection tubes used in a healthcare setting. Important process steps were identified, and each step was investigated, revealing insightful findings. These steps, starting with the decontamination of tubes to finally creating a molded dummy shape, provided the confidence that recycling material from used blood collection tubes was possible. It also educated the researchers on which methods work and which don't. Finally, and most importantly, this study reinforced the importance of collaboration across the entire value chain to create innovative solutions to challenging problems.

Purpose

The purpose of the feasibility study was to investigate whether used blood collection tubes can be cleaned and the tube material mechanically recycled, without compromising hygiene, safety and quality of the material.

The feasibility study therefore tested cleaning scenarios and the ability of the cleaned tubes to be shredded to produce flakes, which could then be molded.

The results of the study provide the foundation for the partners to assess the viability of establishing a recycling model for blood collection tubes, and to make decisions about further steps to optimise the cleaning and recycling processes, and develop and implement the recycling model.

The study also provides general knowledge about the potential of recycling plastics product from the hazardous waste fraction in healthcare laboratories, in order to increase circularity in healthcare and reduce the climate footprint of the healthcare sector.

Blood collection tubes were chosen as the object of the investigation because they represent large amounts of homogeneous high quality PET material, which is currently disposed and incinerated as hazardous waste. In the Region of Southern Denmark alone, 7 mio. tubes are used and incinerated every year, totaling approximately 21 tonnes of PET plastic.

REUSE VS RECYCLING

Blood collection tubes are made of PET plastic and are designed to be single use products. Considering the use case, nature of the application, and nature of the plastic, these tubes are not suitable for being cleaned and reused unlike more durable devices used in the healthcare sector which are made from materials like glass or metal. However, PET as a material is highly suitable for recycling, especially in closed loops, and generally has a lower carbon footprint than most other materials across its lifecycle (with multiple circles of recycling). Consequently, the team has explored the pathway of recycling the PET plastic from these tubes instead of finding ways of reusing them.

Partners

The feasibility study was executed in a public-private collaboration between experts and key representatives from the potential value chain of a recycling model for blood collection tubes.

- **Odense University Hospital, Department of Clinical Biochemistry** was the lead partner, providing the healthcare sector perspective and used tubes from the hospital.
- **The Health Innovation Centre of Southern Denmark** was the Project Manager, in charge of planning, coordination, follow-up and reporting on the feasibility study collaboration and activities.
- **Danish Technological Institute** was involved as the plastics expert, in charge of testing label removal, shredding, washing and drying the used tubes and assessing the quality.
- **Global Material & Asset Fond** and **EcoFITT ApS** were involved as an industry representative of circular models for plastic products, in charge of molding test and comparative analysis of resin pellets.
- **BD (Becton, Dickinson and Company)** was involved as a major industry representative of manufacturers of blood collection tubes, in charge of providing data on requirements for resin material, providing raw material for comparison and assessing the potential of bringing recycled resin material into a circular loop.

The feasibility study was financed by **the Regional Council of the Region of Southern Denmark**, as an innovation initiative to reduce the climate footprint of the region's healthcare operations.

Overall Conclusions

The results from this study demonstrate the feasibility of decontaminating and processing PET material from used blood collection tubes. Results also showed that the processed PET

material could successfully be molded into a dummy article. It should be noted that using the recycled material to make new blood collection tubes was not investigated in this study.

In this study partners across the value chain collaborated to evaluate appropriate methods for decontamination, shredding, cleaning, and molding of these PET blood collection tubes. These steps have been performed successfully on a feasibility scale and will be further discussed in the later sections of this report. Additional research is needed to further refine some of these steps based on the findings of this feasibility study, including scale up considerations for ultimately enabling circular economy solutions.

Key process steps evaluated in this feasibility study

Industry partners from across the value chain are interested in further investigating and becoming a part of a recycling system for healthcare laboratory plastics.

In the Region of Southern Denmark we are committed to reducing the climate impact of our healthcare operations, e.g. through engaging in partnerships with suppliers to reduce impact across the value chain, reduce waste and increase circularity.

- Karsten Uno Petersen, Member of Regional Council, Region of Southern Denmark

As a large hospital and major end-user of single-use healthcare products, we at Odense University Hospital have an important role in enabling the transition towards more sustainable hospital operations.

- Mads Nybo, Chief Physician, Department of Clinical Biochemistry, OUH

BD is committed to evaluating sustainability-focused circular economy solutions for its product portfolio and looks forward to continued partnership with like-minded partners in this journey.

- Amit Limaye, Director, Sustainable Medical Technologies Institute (SMTI)

As an RTO, it is the ambition of the Danish Technological Institute to help translate society's green agenda into concrete technological solutions and accelerate the green transition of companies, e.g. within the healthcare sector's transition to circular and sustainable use of materials resources.

- Peter Sommer-Larsen, Business Manager, Materials, Danish Technological Institute (DTI)

The Health Innovation Centre of Southern Denmark facilitates collaboration and partnerships across the value chain to develop innovative solutions for green transition of the healthcare sector.

- Caroline Strudwick, Project Manager, Health Innovation Centre of Southern Denmark (SDSI)

We were excited to contribute our circular knowledge in the first step towards a closed-loop for contaminated blood collection tubes.

- Ingo Walterscheid, CEO, Global Material & Asset Fond (GMAF)

Conclusions from Tests

Microbial tests

Tests

Test 1 experimented with different cleaning methods (emptying, rinsing, cleaning with detergent).
Test 2 tested heat treatment to ensure safety in further processing of used tubes in the feasibility test.

Main conclusions

Test 1: The tests revealed that it is possible to lower the microbial load by cleaning the tubes, however the tested methods did not bring down the microbial levels sufficiently.
Test 2: Heat treatment reduced the microbial burden to under detection limit. However, there might be other methods that can achieve the same outcome, while enabling good resin output quality and using a decontamination process with a lower climate impact.
Guidelines and microbial target levels are not currently defined in relation to transporting and recycling used blood collection tubes and other similar single-use plastics products in healthcare.

Suggestions for further research

- We need to both define realistic microbial load in used blood collection tubes, and determine relevant microbial target levels in the cleaned tubes and requirements for the cleaning procedure.
- It is necessary to further optimise the cleaning procedures by testing other methods and identifying the optimal methods, which will reach the determined target levels with the least climate- and environmental impact, as well as impact on quality.

- In this connection we will be aware of hygiene regulations and standards, as well as health and safety aspects.
- We need to develop automated solutions for the local cleaning processes.

Label Removal Tests

Tests

Tubes are labelled with two different paper labels: one type from the tube manufacturer and, on top of that, another label used by the hospital or the general practitioner. Labels are glued to the tubes and the underlying labels.
After shredding the tubes to flakes, label remnants were removed by washing. It was demonstrated that no traces of paper or glue remains after a hot alkali wash at 60 °C.
Full tubes (non-shredded) were also washed using the same procedure, but label remnants were found to get stuck inside the tubes, and could not be removed easily.

A second test on 1,000 new labelled tubes were shredded, washed in hot alkali for two hours, rinsed and dried and an amount of 1.9 kg was later used in the recycling molding test. In a side track, it was demonstrated that caps and elastomeric sealing on the tubes could be shredded and separated for recycling. All components of the blood collection tube supply can hence be prepared for recycling.

Main conclusions

The established industry method for removing labels will also work on blood collection tubes. The feasibility test was a pure laboratory test but contained cleansing steps found in industrial scale washing processes for PET bottles recycling. A typical series of processes found in such plants include an air classifier for blowing loose paper label pieces away from the PET flakes; followed by a hot alkali wash; floatation separation; a friction wash for final cleaning; and drying processes.
The washing process will only work on shredded tubes.
Hence all components of the blood collection tubes may enter a circular resource cycle and adding the tray and cap components to test tube recycling may create a stronger economic and more sustainable solution for the hospitals.

Suggestions for further research

- We need to further investigate label removal options in relation to functionality vs. sustainability, to find the optimal method on an industrial scale.
- We should investigate alternative label options (e.g. PP-labels).
- We need to find a value chain partner who can remove the labels.
- A value chain for recycling or reuse of caps needs to be investigated and its economical and sustainable feasibility evaluated.

Recycling – Preparation of raw material

Tests

Decontamination, shredding and washing of used blood collection tubes for preparation of raw materials to the recycling molding test.
Two fractions were treated: approximately 10 kg of used blood collection tubes (3,000 tubes) that were emptied for blood at OUH without further cleaning and shipped to DTI. In addition, 40 kg of new unlabeled blood collection tubes. The purpose was to generate a raw materials batch that could be fed into the injection molders hopper in a stream that contained similar material and where products made from the 10 kg of used blood collection tubes could be collected in the production run.

Three batches of recovered PET material from tubes were created by shredding the tubes into flakes and provided for third-party injection molding at Otto Männer GmbH in Bahlingen, Germany:

A. Recovered PET from unlabelled and unwashed freshly produced blood collection tubes from BD; in total 38.7 kg.
B. Recovered PET from labelled and used blood collection tubes, in total 8.0 kg. They were decontaminated by 24 hours high temperature sterilization in oven (120 °C). After label removal in hot alkali wash and drying, they were shredded.
C. Recovered PET from labelled and unused blood test tubes, in total 1.9 kg. After label removal in hot alkali wash and drying, they were shredded.

The purpose of the testing was to evaluate the readiness of the B and C batches for injection molding.

Main conclusions

Emptying tubes at the source (e.g. Department of Clinical Biochemistry at OUH) is not sufficient for shipping as non-hazardous waste because the amount of blood contained in each tube adds up to litres even for a small batch of 3,000 tubes. Hence a conclusion is that a washing process at the source is required.
The washing procedure and the decontamination of the tubes received did not harm the materials' ability to be remolded – see next section.
The test found impurities in the shredded material; however, it is unknown where the impurities stem from but most likely from the shredder itself. In an industrial recycling process, a dedicated shredder would be used and maintained for clean production.
Single flakes – typically 1 out of 100 – was found to be discoloured yellowish in the fraction prepared from the used blood collection tubes. The two other batches showed no discolouring. FTIR analysis of the discoloured flakes did not show the origin of the impurity.
The impurities did not harm the ability for subsequent molding.

Suggestions for further research

- We need to further investigate, how we can optimise processes to reduce impurities.

- We need to investigate the presence and influence of the tube contents (such as heparin, gel) and the cleaning materials.
- And to which degree an industrial process could remove contaminants from the recycled material.
- We need to identify the full recycling value chain and relevant partners in a circular business model.

Recycling - Molding Test

Tests

Tests were performed at Otto Männer GmbH (Barnes Group) in Bahlingen a.K., Germany
Injection molding of 3 batches of recovered PET material (resin);
A: material from unlabelled and unwashed freshly produced blood collection tubes from BD (38.7 kg).
B: material from labelled and used blood collection tubes from OUH – decontaminated by 24 hours oven sterilisation at 120 ^{O}C, label removal in hot alkali wash, drying and shredding (8.0 kg).
C: material from labelled and unused blood collection tubes – label removal in hot alkali wash, drying and shredding (1.9 kg).
Batch A and C were tested in order to have a reference for subsequent comparative analysis.
In order to enable a quick turnaround and minimise expenses, an existing mold at Otto Männer GmbH was used to check for moldability of the recovered material.

Main conclusions

The injection molding succeeded with all 3 batches of recovered material. The results of the molding test are surprisingly good, especially considering the fact that flakes were directly used for molding, instead of standard processing of recycled PET material.
There are impurities in all three batches of recovered material.
The transparency of the molded material is lower than usual transparency within the industry.
The quality of the material is affected by small variables in temperature and pressure during the molding process.
It is challenging if the shredded material is non-homogenous in size.

Suggestions for further research

- We need to further investigate how the recycling processes can be optimised to reduce impurities and haze, while increasing transparency. This will need to be done with larger quantities to ensure validated results.
- Together with BD, we will investigate whether current transparency requirements for blood collection tubes can be re-evaluated. We need to involve the healthcare staff to define relevant transparent levels in accordance with actual needs for optical transparency in the clinical workflows.
- We need to investigate the quality measures of recycled material for making medical devices, while ensuring safety and efficacy of the end product.

Comparative Analysis

Tests

The mold available for the molding test produced a dummy part of approximately the same weight and wall thickness as the tubes but with a different geometric shape. Hence simple comparison between the product and the original tube was pointless. Instead, a comparison between the molded dummy parts made from each of the three batches was performed using qualitative evaluation of appearance of the dummy part and quantitative measurements of haze and transmission through its bottom section.

Main conclusions

The quantitative tests showed minimal standard deviations in transmission and haze between measurements of four samples from each batch.
The transmission level was slightly smaller for batch B (material from used tubes) compared to batches A and C, however the difference was not statistically significant.
Haze level was the same for all 3 batches of material.
The transparency level of the molded material is lower than new blood collection tubes, however OUH laboratory consider the achieved transparency level in the test mold satisfactory for clinical needs.
Visual appearance, tactile feeling, and apparent mechanical compliance is indistinguishable between products from the three batches.

Suggestions for further research

- We need to perform an in-depth comparative analysis of material properties on larger quantities to investigate optical and mechanical properties, as well as product stability and thermal properties.
- The material needs to be injection molded in the correct blood collection tube shape in order to achieve proper comparability.
- We need to validate the quality of resin pellets from the optimised cleaning and recycling processes, described above, against industry standards and requirements from manufacturers (e.g. BD).
- We need to investigate the quality measures of recycled material for making medical devices, while ensuring safety and efficacy of the end product, this includes leachables testing.

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