A Behavioral Study of Digital Technology for Improving Post-Operative Incentive Spirometer Adherence

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Scholarly Report Title: A Behavioral Study of Digital Technology for Improving Post-Operative Incentive Spirometer Adherence

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**Title:** A Behavioral Study of Digital Technology for Improving Post-Operative Incentive Spirometer Adherence

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**Purpose:** This study seeks to determine whether incentive spirometer (IS) data gathered via a smartphone platform can be utilized to determine baseline adherence to prescribed IS exercises, as well as improve patient adherence in the post-operative period. A customized smartphone-based device will be the primary intervention and will record as well as encourage use of prescribed spirometer exercises through a connected spirometer device (Smart Peak Flow™) and smartphone-based app. By establishing a dose-response relationship between IS and post-operative pulmonary complications (PPCs), we can make a more informed decision regarding the use of IS in the post-operative period.

**Methods:** This study is a prospective, randomized, participant blinded, single center, clinical trial. Based on our planned analysis, we expect to enroll 50 patients (25 in each arm). The control group will be given the BIDMC standard Voldyne™ IS with an attached Smart Peak Flow™ device to passively record usage. The study group will be given the Smart Peak Flow™ device connected to an android smartphone to record usage. Patients in the study group will also utilize a smartphone application to view their usage and receive encouragement to continue using their device.

**Results:** Due to delays in device development, outcomes data are not currently available for analysis. However, we plan to begin recruiting participants over the next two to three months. The primary endpoint is patient adherence to prescribed IS exercises in the perioperative period. Secondary outcomes are largely clinical and included PPCs as measured by atelectasis, respiratory failure, tracheobronchial infection, or pneumonia. Other secondary measures include total mortality from respiratory causes, all other post-op complications, length of in hospital stay, all-cause mortality, and cost analysis.

**Conclusions:** Incentive spirometry has been a mainstay of affordable PPC prevention for decades, but a lack of adherence data (whether due to imperfect use or imperfect data capture) has led many to question the true clinical effectiveness of this intervention. Our study utilizes a custom IS and Smart Peak Flow™ meter to measure and record baseline adherence data on a
smartphone platform. Once we have a more reliable measure of baseline adherence, we can analyze the dose-response relationship between IS exercises and the incidence of PPCs. This will provide more conclusive evidence to support either the continued use of post-operative IS or its discontinuation.
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GLOSSARY OF ABBREVIATIONS

- IS = incentive spirometer
- ISy = incentive spirometry
- NSQIP = National Surgical Quality Improvement Project
- PPC = postoperative pulmonary complication
- SDK = software development kit
SECTION 1: INTRODUCTION

Postoperative pulmonary complications (PPC) have been an established risk of surgery for well over a century, with large scale studies published as early as 1933. More recently, the National Surgical Quality Improvement Project (NSQIP) examined the incremental hospital costs associated with postoperative complications in patients undergoing general and vascular surgery. Adjusting for procedure complexity, patient characteristics, and other complications, respiratory complications had the second highest incidence, the largest attributable cost, and were associated with a significantly increased length of stay. With multiple studies suggesting incidences anywhere between 2% and 90%, PPCs remain a common, serious, and expensive problem.

It is currently thought that the impact of anesthesia, pain of surgery, and immobility in the postoperative period are the primary drivers of the shallow breaths, atelectasis, and impaired mucociliary clearance that lead to PPCs, but theories implicating impaired respiratory function as an etiology can be traced back to the 1930s. It was not until the 1950s, however, that deep breathing exercises were identified as a means of reducing their incidence, especially when introduced preoperatively. By the 1970s, it was determined that sustained inspiration was key to effective deep breathing exercises, leading to the creation of the Bartlett-Edwards incentive spirometer (IS) and its establishment as the standard of postoperative pulmonary care.

Since then, incentive spirometry (ISy) has become the mainstay of affordable PPC prevention, but studies regarding its clinical effectiveness have been mixed and frequently cite lack of patient adherence or imperfect data acquisition as an explanation for this uncertainty. This has lead some hospitals to discontinue use of ISy altogether. Patients are typically instructed to inhale deeply and slowly into an IS device for several breaths up to six times per hour. When used as prescribed, tracking this amount of data using manual patient logs or house staff visits becomes unreliable and unsustainable. Narayanan reiterated these limitations in a recent review and concluded that compliance data needed to be obtained using reliable and standardized methods so as to facilitate valid conclusions regarding the effectiveness of IS.
The purpose of this study is threefold. First, to create a digital incentive spirometer capable of measuring and recording IS use using a smartphone platform. Second, to use this data to determine baseline adherence. Third, to assess how IS data gathered via a smartphone platform can be utilized to improve patient adherence to prescribed IS exercises.

SECTION 2: STUDENT ROLE

I joined this project shortly after inception as a research assistant. In general, I have aided in study design, device development, recruitment and data collection, and the preparation of abstracts, posters, and manuscripts.

Study Design
I am listed on the original IRB application for this study and have remained involved in all major modifications to the study design. I have provided advice and critiques where appropriate. I also performed an extensive literature review at the start of this project to help elucidate the history of incentive spirometers and establish an appropriate context for the study.

Device Development
Our digital incentive spirometer requires several 3D printed parts. In researching various materials to select an appropriate filament type, I identified a gap in the literature regarding the health and environmental implications of 3D printed materials in medical devices. I researched these materials extensively in order to select the safest and most appropriate (durable, flexible, limited off gassing, etc.) material for our device. During the testing/calibration phase, I performed a literature review of methodologies used for similar devices in order to help design a thoughtful and scientifically-driven strategy for measuring the accuracy and reliability of our device.

Recruitment & Data Collection
Once the device is finalized, I will participate in its deployment during participant recruitment. I will be responsible for consenting patients, teaching them how to use the device, maintaining the devices, and collecting the SD cards containing use data.

Preparation of Abstracts, Poster, & Manuscripts
Following my literature review on the health and environmental implications of various 3D filaments, I was able to compose and submit an abstract to the 2019 Society for Technology in Anesthesia (STA) Annual Meeting (see Appendix 1). Upon its acceptance, I created a poster for oral and visual presentation at the conference (see Appendix 2). I am currently preparing an abstract on the testing/calibration of our device based on the relevant literature, though this may become a part of the larger manuscript we will submit at the end of this study, of which I will also have a significant role in preparing.

SECTION 3: METHODS

Device Construction
In order to design a device capable of answering our study question, we needed to consider the following aspects: (1) how closely the device in the passive arm would resemble the standard of care, (2) how we could detect and/or measure use in order to determine adherence, (3) how to record this information in a reliable and accurate way, (4) how to minimize variability between devices in the passive and active arms, (5) how to communicate with the patient in order to encourage use beyond baseline adherence.

We wanted our device to resemble the standard of care as closely as possible so as to mimic what patients would experience in a community hospital setting. To achieve this, we selected a Voldyne™ incentive spirometer (standard of care at BIDMC) as our base device (see Figure 1). To this, we added the following components (see Figures 3-8):

1. an in-line Smart Peak Flow™ meter connected via custom 3D printed adaptors
2. a 3D printed overhead compartment containing an infrared LED, circuit, and battery
3. a 3D printed base containing an Android smartphone connected to the Smart Peak Flow™ meter via head jack cable

Initially, we planned to place a strip of copper capacitance tape along the handle of the IS, which would allow us to detect when the device was picked up. However, we were concerned that the act of picking up the IS was not an accurate reflection of use. For example, the patient or nurse may pick up the IS to move it, but not necessarily use it, or the patient may pick up the device to use it, but not necessarily use it correctly or effectively. Instead, we decided that the most reliable marker of use was airflow, as this reflects the proposed therapeutic function of the
device: slow, sustained inhalation. To detect this, we placed a Smart Peak Flow™ meter in line with the air tubing of the IS.

The Smart Peak Flow™ meter is a compact, portable device designed to measure forced expiratory volume in one second (FEV1) in patients with asthma (see Figure 2). It consists of a small fan and a light sensor housed within a cylindrical tube and a headphone jack that plugs directly into a cell phone. As users exhale into the device, the fan spins. The light sensor then detects the rate at which the light is obscured by the fan blades and converts this to flow. In this way, it can calculate FEV1.

By incorporating the Smart Peak Flow™ meter into the air tubing, we were able to detect our desired marker of IS use. We accommodated the difference in size between the IS tubing and the Smart Peak Flow™ opening by creating custom 3D printed adaptors (see Figure 6).

During initial testing, we encountered an issue with flow detection in low light settings. The Smart Peak Flow™ meter was designed to detect high flow under natural light conditions, but the hospital environment often uses low or fluorescent lighting. As a result, we were having difficulty capturing low flow use in these environments. We took two steps to overcome this. First, we created a 3D printed box that sits directly over the light inlet of the Smart Peak Flow™ meter. The box contains a simple LED light circuit and battery that provides a constant and consistent light source for the sensor (see Figures 4-5). This solved the low light problem, but also required that we choose an intensity of light that would be strong enough to capture low flow without increasing the false positive rate.

Second, we made modifications to the software development kit (SDK) that came with the Smart Peak Flow™ meter. Its original design included a self-imposed low flow cutoff beyond which it would not measure flow. It achieves this by measuring both flow rate and intensity, specifically using the intensity to differentiate between low flow and noise. This made sense given the device was designed to measure high flow, but was too high to accept the low flows we expected. Along with our new constant light source, modifications to these cutoffs allowed us to more reliably detect and measure low air flow.
Next, we designed a self-contained method for recording this information. As the Smart Peak Flow™ meter was designed to work with a mobile device, we purchased an Android phone and programmed it to run only the software necessary to record data. We 3D printed a custom casing that snapped onto the bottom of the IS and contained the phone (see Figure 7). A removable plate was incorporated into the design so that we could access the phone without taking the case apart (see Figure 8). In addition, an opening was left on one side of the case to allow an auxiliary cable to attach the Smart Peak Flow™ meter to the phone.

The filament material used to create the 3D printed components for the device is composed of acrylonitrile butadiene styrene (ABS), a durable, long-lasting thermoplastic. This is the same material used to create LEGO™ building blocks. As we continue to produce the components for these devices, we would like to move more towards environmentally-conscious materials such of polylactic acid (PLA), which is made from natural materials like corn and is compostable.

Device Testing/Calibration
With the device completed, we are currently entering the testing and calibration phase. Given the substantial modifications thus far, we do not anticipate any major changes. Rather, we anticipate only minor modifications to the SKD as we test the precision and accuracy of the device. We intend to do this by attaching the end of the IS tubing (where the patient would place their mouth) to a ventilator capable of delivering a defined volume of air at a specific flow rate. We will anticipate these flow rates based on initial testing among volunteers. Once we can demonstrate an acceptable level of precision and accuracy, we will deploy the devices to our study participants.

Digital Incentive Spirometer Study
This study is a prospective, randomized, participant blinded, single center, clinical trial to ascertain whether a smartphone connected digital incentive spirometer, the Smart Peak Flow™, can improve patient adherence to prescribed incentive spirometer exercises. A control group will be given the BIDMC standard Voldyne™ Incentive Spirometer with an attached Smart Peak Flow™ device to record patient use of the Voldyne™ IS in a passive manner. The study group will be given the Smart Peak Flow™ connected to an android motherboard (microcomputer, aka smartphone) running Android OS, that will then record use and store this data on the smartphone itself. The patient will then use an app on the BIDMC provided smartphone to view their usage and receive encouragement to continue using their device. All data on use will be
recorded locally and there will be no internet connection or communication with patient through this device at any time.

The study is designed as a technology evaluation to assess feasibility, usability and assess for early impact on our outcome measures. This study will include 50 participants that are scheduled for elective surgery at BIDMC and require an inpatient stay of at least 1 day post-operatively. We expect to recruit 16 patients in the treatment and control, but cannot guarantee the exact ratio. All patients will be seen in the Pre-Operative Unit prior to surgery where the recruiting will take place.

Inclusion Criteria:
- ASA 1-3 patients undergoing elective Surgery at BIDMC requiring Incentive Spirometer use in the post-op period
- Greater than 18 years of age.
- Able to understand and sign a study consent form
- Able to understand and utilize a smartphone application

Exclusion Criteria
- Diagnosis of Obstructive Sleep Apnea (OSA), treatment with CPAP or BiPAP for OSA
- Lack of regular smartphone use, or visual, mental or motor impairment that impedes use of smartphone
- ASA 4 or greater, any ASA-E status (emergency surgical procedure)
- Suspected or established respiratory infection
- Previous spontaneous pneumothorax
- Severe pulmonary disease, or use of home O2
- Does not speak or understand English

Subjects will be distributed among different genders and races and will not be excluded on the basis of gender or race.

At the time of enrollment, users who meet the inclusion criteria and none of the exclusion criteria will be asked to opt in to the study. Users will read information about the study and research staff will explain what it means to “opt in”. Prospective participants will be given ample time to read the informed consent form and ask any questions.
Once enrolled, users will be randomized electronically to either the study group or control group. Those that are randomized to the control group will have no further training or instructions at the Pre-Operative Unit prior to surgery, though they will receive standard IS exercise instructions as per standard of care once they meet discharge criteria from the Post Anesthesia Care Unit (PACU). Those that are in the study group will be instructed on how to use the smartphone application and device which will then be provided to them in the PACU after their surgery, where they will be re-educated on device usage once they meet discharge criteria from the PACU.

SECTION 4: RESULTS

Digital Incentive Spirometer Study
Due to delays in device development, outcomes data are not currently available for analysis. However, we plan to begin recruiting participants over the next two to three months. See below for planned data analysis.

Data Analysis
The study involves two groups, an intervention and control, with a continuous endpoint of percentage of compliance. It is expected to have an alpha of 0.05 with a power of 80%. Anticipated compliance for the intervention is 70% (assumed SD=+/- 20), with anticipated adherence amongst the control of 50%. Therefore, the anticipated sample size is 50 patients, with 25 to the intervention and 25 to the control.

It should be noted that this is a pilot study, and since the primary outcome of compliance has yet to be adequately measured by any prior trials, the numbers above are our hypothesized compliance numbers. The ultimate goal is to gather information on compliance rates to assist in the design of a more definitive trial.

All participants agreeing to take part in the study will be randomized to either control or intervention. It is expected that the dropout rate will be higher for the intervention than the control group, as the control group is utilizing a device that is part of the standard of care. It is difficult to estimate the dropout rate, but it may be close to 10% and we will seek to replace those subjects who dropped out with additional subjects to ensure statistical power.
Biostatistical Methods:
The primary endpoint will be patient adherence to the prescribed use of incentive spirometer-based exercises in the perioperative period. The post-operative period is defined as when the patient meets criteria for discharge from PACU to when they are discharged from the hospital. The times measured for adherence to the incentive spirometer will be considered time of discharge from PACU on day of surgery until 8pm on day of surgery, then each subsequent post-operative day in the hospital will have adherence considered from time patient receives breakfast until time patient receives dinner, in order to remove any periods of sleep from the study period.

Secondary outcomes will largely be clinical and derived from the patient medical record as part of their normal care. These secondary outcomes include post-operative pulmonary complications as measured by atelectasis (radiographic, tomographic, or bronchoscopic diagnosis), respiratory failure (radiographic diagnosis in patients with signs of acute respiratory symptoms such as tracheobronchial purulent secretions, fever (>38c) or increased WBC count (>10k), tracheobronchial infection or pneumonia as defined by radiological criteria. Other secondary measures include total mortality from respiratory causes, all other post-op complications, length of in hospital stay, all-cause mortality and cost analysis. For dichotomous outcomes the primary measure of treatment effect will be relative risk with 95% confidence interval. Our primary analysis will be to compare the adherence rates, based on comparison of prescribed versus performed spirometer use. Staff within the Anesthesia Department will assist with statistical analysis design.

SECTION 5: DISCUSSION, LIMITATION, CONCLUSIONS & SUGGESTIONS FOR FUTURE WORK

Incentive spirometry has been a mainstay of affordable PPC prevention for decades, but a lack of adherence data (whether due to imperfect use or imperfect data capture) has led many to question the true clinical effectiveness of this intervention. In lieu of this uncertainty, some hospitals have chosen to discontinue ISy altogether. Our study sought to create a device capable of measuring and recording baseline adherence data using a smartphone platform. To do this, we incorporated a Smart Peak Flow™ meter into the air tubing using 3D printed adaptors and connected it to a self-contained Android smartphone housed in a 3D printed base.
One the device is formally tested and calibrated, it will be deployed to study participants in the passive arm and used to ascertain baseline adherence to ISy exercises. We will then transition to the active arm of the study, in which we use the Smart Peak Flow™ meter connected to a smartphone device to encourage ISy exercises. Once we obtain this data, we hope to be able to bridge the gap in the literature regarding adherence and hopefully ascertain whether a dose-response relationship exists between ISy and PCPs.

A major limitation of this current study is a lack of outcomes data for analysis, though this is temporary and will be resolved once we complete our device development phase and proceed to the clinical arms of the study. We anticipate this will begin within the next 2-3 months. At that point, another potential limitation to consider will be the Hawthorne effect, in which subjects alter their behavior due to the awareness of being observed. If patients demonstrate more adherence than they normally would due to the observational nature of the study, our results may demonstrate more benefit than can reasonably be expected in community clinical practice. In addition, awareness of the study could influence the emphasis surgical and/or nursing teams place on use of the device, which could encourage greater use under the study conditions.

Once we have a more reliable measure of baseline adherence, we can analyze the dose-response relationship between ISy exercises and the incidence of PPCs. This will provide more conclusive evidence to support either the continued use of post-operative ISy exercises or perhaps further discontinuation. If we demonstrate a clear benefit with IS, we may want to refocus our efforts on ways to track and improve adherence in a more cost-effective way and distribute this technology more broadly. We can also consider incorporating ISy into perioperative checklists such as ERAS (Early Recovery After Surgery) to improve postoperative outcomes.

Interestingly, there is also recent interest in the space industry regarding medical and surgical management of patients on deep space exploration missions. As these missions increase in length and distance, doctors and engineers will need to consider the possibility of long-term recovery from unexpected trauma and surgical procedures in space. If we demonstrate a clear role for ISy in the post-operative terrestrial environment, it may be beneficial to translate this technology to the extraterrestrial microgravity environment.

SECTION 6: ACKNOWLEDGEMENTS
I would like to thank my mentor and PI, John Pearson, MD, who provided the initial concept for this project and was instrumental in all aspects of study design, device creation, and clinical trial execution. I would also like to thank Charles Safran, MD and the Division of Clinical informatics at BIDMC for providing funding and support for our project. I would like to thank Shao Yuan for his vital contributions to device design and Android support. Lastly, I would like to thank my advisor Mary Catherine Arbour, MD for her support and advice along the way.

REFERENCES


FIGURES

Figure 1. Voldyne™ incentive spirometer.

Figure 2. Smart Peak Flow™ meter shown attached to cell phone.

Figure 3. Digital incentive spirometer.
Figure 4. Exposed LED housing demonstrating LED battery.
Figure 5. Exposed LED housing demonstrating LED circuit (LED battery removed).
Figure 6. In-line Smart Peak Flow™ device between 3D printed flow connectors and LED housing above (cover removed).
Figure 7. 3D printed base with auxiliary cable connecting Smart Peak Flow™ device and internal smartphone (not visible).
Figure 8. 3D printed base with auxiliary cable connecting Smart Peak Flow™ device and internal smartphone.
APPENDIX 1. 2019 STA Conference abstract.

ABSTRACT TITLE. REVIEW OF THE MEDICAL AND ENVIRONMENTAL IMPLICATIONS OF ADDITIVE MANUFACTURING (3D PRINTING) FILMMENTS

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Introduction: Since the advent of additive manufacturing (AM) in the mid-1980’s, the use of 3D printing has expanded and diversified at an exponential rate.1-4 Largely driven by innovation in science and technology and bolstered by the increasing availability and affordability of printers, materials, and design software, AM continues to create new opportunities for novel and unique printed products. Early medical applications focused predominantly on individualized surgical and dental implants, but over the last two decades, this has expanded to include perioperative planning, pharmaceutical drug delivery, bioprinting, prosthetics, simulation models, and more.5-8 Fused deposition modeling (FDM), a type of material extrusion, is the most common 3D printing method and is used for many of these applications. It utilizes filaments of varying size, color, and chemical composition to produce objects of differing strength, durability, flexibility, and function.6 As this variety increases, however, so must the medical and environmental considerations used in choosing a particular filament. In our review, we sought to evaluate the medical and environmental implications of three of the most common filaments used in FDM: PLA (polylactic acid), ABS (acrylonitrile butadiene styrene), and PETG (polyethylene terephthalate glycol-modified).

Methods: A literature review was performed using PubMed, Web of Science, and IEEE Xplore Digital Library. Where available, material safety data sheets (MSDS) were also reviewed from various manufacturers. Particular attention was paid to the following stages of filament use: production, heating/deposition, degradation, and disposal.

Results: Despite an increasing rate of publications related to 3D printing, there remains a paucity of evidence regarding the health, safety, and environmental implications of various filaments used in FDM.4,7-10 For example, while PLA is generally regarded as the most eco-friendly and sustainable option of the three due to its natural composition, limited research suggests that the resources necessary to produce its source crops may actually offset this advantage.7,11 By contrast, the health and environmental effects of the heating and deposition process have been far better studied. All three filaments produce volatile organic compounds (VOC) and ultrafine particles (UPF) that may lead to skin, pulmonary, and mucosal irritation.12-15 ABS off gases most VOCs, including styrene (a possible carcinogen), while PLA off gases the least.13,15 This can change if additives are incorporated into the base material to change its properties, but because this information is frequently proprietary, it is difficult to evaluate.4 In addition, the MSDS for each filament varies by manufacturer and often does not include information on said additives or melting/decomposition temperatures, product stability, cleaning/sterilization instructions/limitations, specific health effects, or disposal options.4 There is also scarce evidence regarding the stability of these products once the final product is handled, cleaned, or otherwise used for its intended purpose.3

Conclusion: The limitations of such specific health and safety data make it difficult to gauge whether one material is superior to another. Given the rapid expansion of this technology for medical use, this creates the potential for both short- and long-term harm to patients, practitioners, and the environment. For this reason, we recommend that further research be conducted that focuses on how the precise chemical composition of these materials affects the health and safety of those in contact with the materials during heating/deposition and use, as well as the environmental implications of its production, degradation, and disposal. Furthermore, we advocate for regulatory clarification and increased transparency regarding these materials to help guide the choosing of safe and appropriate materials based on the intended use of the final product.

INTRODUCTION

- Interest in 3D printing has exploded since its inception in the mid 1980s, especially over the past decade (see Figure 1). Early medical applications focused on individual surgical and dental implants, while more recent use has included preoperative planning, pharmaceutical drug delivery, bioprinting, prosthetics, simulation models, and more.
- Fused deposition modeling (FDM) is the most common 3D print method.
- FDM utilizes filaments of varying size, color, and chemical composition to produce objects of different strengths, durability, flexibility, and function.
- As the diversity of these filaments and their applications increases, we must carefully consider their potential medical and environmental impact.

METHODS

- Database search: PubMed, Web of Science, IEEE Xplore Digital Library
- Review of available manufacturer material safety data sheets (MSDS)
- Table 1: 3D Filament Comparison Guide

RESULTS

- ABS, PLA, and PETG each have different physical and chemical properties (see Table 1).
- PLA is regarded as the most eco-friendly and sustainable option to produce and dispose of due to its plant-based origin and compostability; PETG is also a good option as it can be produced from recycled materials and is itself recyclable.
- All three produce volatile organic compounds (VOCs) and ultrafine particles (UFP) during heating/deposition that may lead to skin, pulmonary, and mucosal irritation; ABS produces the most (including styrene, a possible carcinogen); PLA the least.
- Information regarding the degradation of these printed materials is limited, though they are generally regarded as stable.
- In general, MSDSs are limited due to proprietary information and often do not include additives that can dramatically alter the physical and chemical properties of a filament.

OBJECTIVE

Evaluate the medical and environmental impact of three of the most common filaments used in FDM:
- ABS (acrylonitrile butadiene styrene)
- PLA (polylactic acid)
- PETG (polyethylene terephthalate, glycol modified)

In particular, evaluate each filament in the following stages:

- Production
- Heating/Deposition
- Degradation
- Disposal

CONCLUSIONS

- Information regarding the relative health and environmental impacts of ABS, PLA, and PETG is limited, creating the potential for both short- and long-term harm to patients, practitioners, and the environment.
- We recommend that further research be conducted regarding the precise chemical composition of these materials and their impact on:
- the health and safety of those in contact with them during heating/deposition and use
- the environment during production, degradation, and disposal
- We advocate for regulatory clarification and increased transparency regarding these materials to help guide the choosing of safe and appropriate materials based on the intended use of the final product.

REFERENCES