The Role of Industry Representatives in the Endoscopy Unit

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Introduction

The modern endoscopy unit is a busy workplace environment. With the patient as the main focus of activity, providers and staff engage in delivering endoscopic services on a daily basis, ranging from basic general endoscopic procedures in an Ambulatory Surgery Center (ASC) to the most advanced complex interventions performed at tertiary academic medical centers.

Our ability to acquire, optimally utilize and maintain endoscopic accessories, devices, and equipment allows provision of high quality endoscopic procedures. Furthermore, the findings of endoscopy often dictate subsequent pharmacotherapy. Industry representatives, acting on behalf of the device, pharmaceutical, and equipment manufacturers, play an important role in helping us achieve this goal. This document was prepared because there is no formal guidance to define the roles and responsibilities of industry representatives in the endoscopy unit.

This document will:

- Describe the role of the industry representative in an endoscopy unit
- Suggest how industry representatives may best engage in that role
- Recommend how to achieve an optimal partnership between industry representatives and the endoscopy unit in the best interest of the patient
- Define the educational and training needs for effective interaction by industry representatives with providers and staff in the endoscopy unit

Hospital credentialing, HIPAA certification, and general code of conduct

A variety of vendor credentialing services are available that health care institutions may use to verify representative credentials and confirm up-to-date compliance with vaccinations and tuberculosis testing, with the intent of increasing safety and reducing liability. Representatives should be in compliance with all credentialing and HIPAA requirements before visiting the endoscopy unit. At the time of a visit they should wear prominent identification that clarifies their role and allows them access to patient care areas, in accordance with the local institutional policies. When present during a procedure, the role of the representative is that of an observer and advisor related to products and a source of information and not as an active participant. Patient consent to have representatives present during a procedure is recommended and should comply with

local institutional policy. Representatives should not take videos or photographs during procedures.

Types of industry representatives

The types of industry representatives encountered in an endoscopy unit may be diverse and are listed in Table 1. The most common are the device or accessory sales representatives (referred to here as product representative). Endoscope or other major equipment sales representatives, pharmaceutical representatives, product specialists, market development managers, scientific li

In addition, when a device or equipment malfunction arises, the representative has a duty and obligation to be available and receptive to the customer's needs and to bring a satisfactory resolution to the problem at hand. This is a critical role, especially in smaller endoscopy units where fewer alternatives (or "back-ups") exist in the event of device malfunction. These units may depend highly on rapid resolution of the problem in order to maintain daily activities.

Major equipment sales and service

Industry representatives are also responsible for sales and service of endoscopes (which often represents the largest capital investment in the unit) and other, specialized types of capital equipment a unit may acquire (eg, endoscopic ultrasound equipment, cholangioscopy, and ablation equipment, etc.). These major investments require in-depth knowledge on part of the representative, not only to facilitate sales but also to address any ongoing issues that may arise with either the equipment or the contract. In many cases, companies assign "product-specialists" to help establish and/or service specific types of equipment. These specialized representatives have more in-depth product specific knowledge, training and expertise and serve as a resource for physicians and unit staff. As with device and accessory representatives, the equipment representative must conduct themselves in compliance with the AdvaMed Code of Ethics on Interactions with Health Care Professionals.[1]

Pharmaceutical representatives

Endoscopy is used to diagnose and treat a variety of GI disorders. Many of these conditions require pharmacotherapy either for the specific GI condition or for the related or underlying disease process. For example, specific GI conditions that are diagnosed with endoscopy include acid peptic disorders (esophagitis, peptic ulcer disease) and inflammatory bowel disease (ulcerative

of the services provided. Introduction to new products and technology is thus a significant service performed by industry representatives and is an important partnership that leads to growth and evolution of endoscopy units over time.

Exciting as new technology is, representatives need to be cognizant of a few caveats. First, there may be an associated incremental cost burden and justification for increased expenditures will be required. Second, repr

and the medico-legal implications related to active participation by a non-clinical observer.

Liaison role and relationship building

Every industry representative has an opportunity to serve a liaison role between the endoscopy unit and the manufacturer. Facilitation of two-way communication, whether it is related to a new device or conflict resolution, is one of the most important functions that representatives serve. They are the "eyes and ears" of the manufacturer in the field and can impact the relationship through their conduct and professionalism. Customizing sales to the needs of the unit, providing timely after-sales service, and simply "being available" when the need arises generates respect for the representative and enhances the reputation of the company they represent. Representatives may help initiate contact and dialog with appropriate personnel within the company to facilitate projects related to device development and innovation in endoscopy, or help support CME events and hands-on workshops. The potential for this role should not be discounted as it can result in enduring partnerships based on mutual trust, respect and the singular focus of providing the best patient care.

Educational requirements and curriculum

Device and pharmaceutical representatives must have extensive knowledge and training regarding both their specific product(s) and, more generally, gastroenterology, hepatology, and endoscopy. These latter areas are common to all representatives and form the basis for a common curriculum. The objectives of this training include understanding basic GI anatomy and physiology, common GI diseases and their endoscopic findings, and the basics of endoscopy and endoscopic therapy. As needed, this education should be supplemented with specific educational topics such as inflammatory bowel disease, gastroesophageal disease, pancreaticobiliary disease, etc. Hands-on training with simulators is especially useful. Certification of successful training is recommended. The ASGE has recently introduced a dedicated industry professional training program (ARIA: ASGE Recognized Industry Representative) that has didactic and hands-on components, designed to help train representatives. Table 3 outlines a suggested curriculum.

Summary and final recommendations

Industry representatives serve an important and multifaceted role in the endoscopy unit. As described above, there are many elements that are necessary for a successful and meaningful relationship with the endoscopy unit, ultimately aimed at enhancing patient care and achieving the highest levels of professional satisfaction for all stakeholders.

Key recommendations are summarized below:

- Appropriate training and education for representatives is essential.

- Corporate educational and training curriculum, preceptorships, ARIA program, etc.

Representatives should be formally credentialed with the hospital(s)/ASC facility, including HIPAA and any other site-specific requirements.

Representatives must comply with AdvaMed and PhRMA codes and local policies on interactions with healthcare professionals.[1,2]

Patient consent is recommended for intra-procedural observation. Representatives should not take videos or photographs during procedures.

During procedures, representatives are expected to provide “guidance only” vis à vis function and technical aspects pertinent to their device or equipment.

Representatives may not participate in a “hands-on” fashion during endoscopic procedures.

Representatives should not advise on clinical decisions or equipment selection for specific procedures or patients.

When in place, the value analysis process for device and pharmaceutical acquisition needs to be respected and followed by representatives. Not doing so may have financial and medico-legal implications.

When introducing new technology to the endoscopy unit, the distinction between FDA-cleared and non-cleared devices and accessories needs to be made clear explicitly.

Formal initial and periodic “in-service” sessions for unit staff and providers are recommended to gain and maintain familiarity with medications and new equipment, especially for complex devices or accessories.

Representatives should request a formal, written physician evaluation/assessment 5(fi)-5ocedures,. to g90 comc7J-15i5 TD-.00/TT1.15ity with maTj diahoTDp225 TD00 T3cxa

As discussed, the role of an industry representative is more significant and impactful than just providing sales and service of endoscopy related equipment and medications. They serve critical roles in facilitating communication between institutions and manufacturers, assist with contract negotiations and information delivery, help with technology and new treatment acquisition, and provide opportunities for hands-on skill and knowledge acquisition for staff.

In many instances, deep, enduring personal and professional relationships are formed between the industry representatives and the endoscopy unit personnel that ultimately enhance the overall quality of the unit and the care of the individual patient.

TABLE 1. Different types of industry representatives

1. Device and accessory sales representative
2. Endoscope and equipment sales representative
3. Pharmaceutical representatives
4. Product support specialists
5. Market development managers
6. Scientific liaisons
7. Senior leadership team members
8. Other (project specific) representatives

TABLE 2. Various roles of industry representatives

1. Device and accessory sales and service
2. Endoscope and major equipment sales and service
3. Introduction and incorporation of new technology
4. Providing equipment related “in-service” for staff
5. Delivering provider and staff education for use of pharmaceuticals
6. Intra-procedural device related support
7. Liaison role

TABLE 3. Curriculum for industry representatives

Gastrointestinal Tract in Health: Basic Anatomy and Physiology

Foregut: Esophagus/Stomach
Midgut: Small Bowel
Hindgut: Colon/Rectum
Hepatopancreaticobiliary

Tools of the Gastroenterologist

Introduction to GI Endoscopy —EGD, Colonoscopy, ERCP, EUS, Enteroscopy
Other Tests Used by Gastroenterologists—pH testing, Manometry, Radiology, Emerging Technologies

Gastrointestinal Tract in Disease: Overview of Major GI Disorders

Foregut: Esophagus and Stomach
Midgut: Small Bowel
Hepatopancreaticobiliary Disease
Colon/Rectum

Hands-on Simulator Training

Basic Scope Handling/Foreign Body Removal

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