Healthcare Delivery Guide

Objectives

- Understand the patient care pathway relative to new technology
- Identify where new technology provides value within the healthcare ecosystem
- Evaluate positioning the technology in order to develop a clinically relevant implementation plan

Outcomes

- Determine where the technology best fits into the value paradigm
- Gain knowledge on and define key parts of the healthcare ecosystem relative to your technology

Next Steps

- Perform the necessary research to identify knowns and unknowns of the clinical pathway
- Complete the Healthcare Delivery Worksheet

Relevant Resources

Regulatory Module

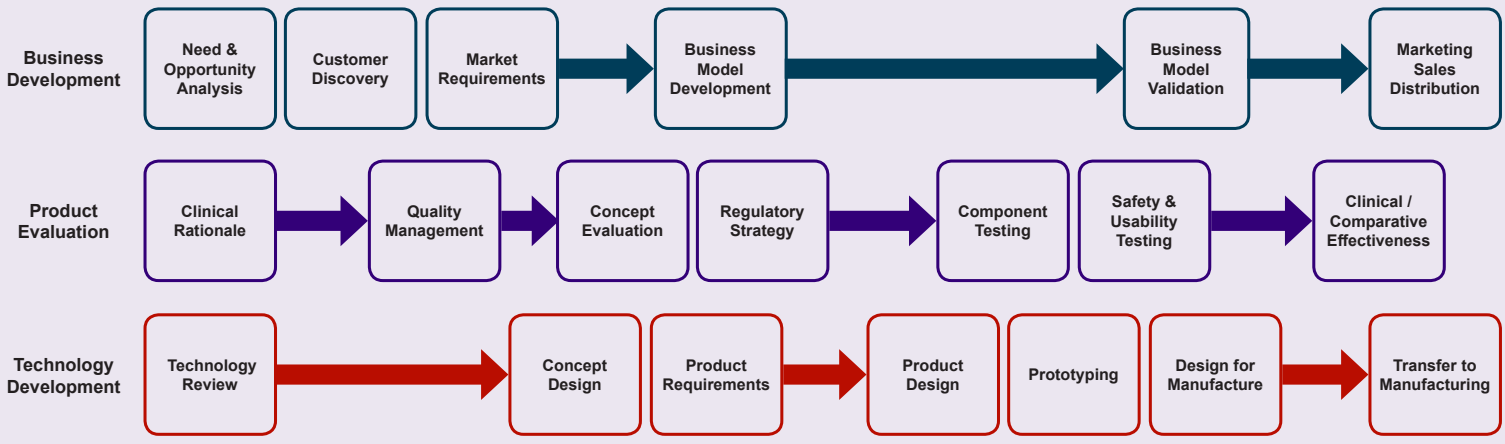
TREAT educational module on regulatory and reimbursement

Institute for Healthcare Improvement

Healthcare Delivery Worksheet

Integrated Care Pathway for Total Joint Arthroplasty

Commercialization Methodology



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Healthcare Delivery

The delivery of healthcare in the United States is a complex ecosystem that can be difficult to navigate. This module is intended to help you, the innovator, understand how your product fits within this ecosystem toward the goal of successful sales, clinical adoption, and implementation. Using this guide, you will assess the patient care pathway and gain an understanding of the value and utility your product will have for patients, providers, and other stakeholders involved in the delivery of healthcare.

Patient Care Pathway

The patient care pathway, or clinical pathway, is defined as and describes the patient experience from first contact with a medical office all the way through to the completion of treatment. Because the clinical pathway for a particular medical condition may differ based on patients' individual circumstances, standardization of care can prove challenging. There may be a single pathway or it may exist in various forms. Pathways may vary between institutions or there may be a national standard or best practice. Thus the readers should not be discouraged by the lack of a sole path and should take into consideration all patient care pathways identified. A patient care pathway includes:

- Stakeholders
    - Patient
    - Care Giver
    - Clinician
- Clinical Care Setting
    - In-patient/Out-patient
    - Surgical
    - Homecare
- Conditions (i.e. symptoms, stages)
- Diagnosis
- Best Practice Guidelines or Current Standard of Care – what are the current standards of care for the condition?
- Outcome

Mapping the patient care pathway begins with identifying strengths, weaknesses, opportunities, and threats for your product and where within the pathway your technology will fit. At this point, you should begin to layout a patient care pathway that includes your product. Something to ask yourself is - will the product be adaptable to the current environment, or will it disrupt the current environment completely?

Refer to the Healthcare Delivery Worksheet that is part of this module to begin laying out the necessary pathway. Figure 1 gives an example of what a patient care pathway broadly entails:

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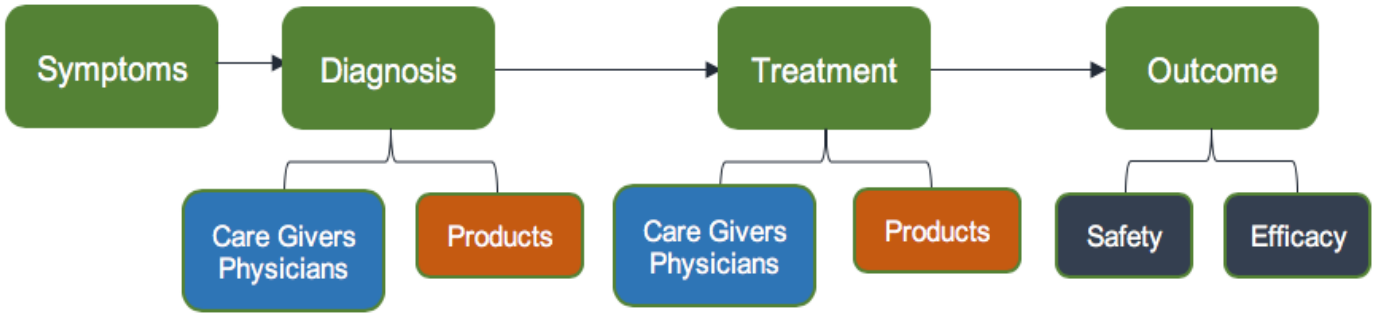
Figure 1: Map of the Patient Care Pathway



In the Healthcare Delivery Worksheet, you will overlay your technology and associated process on the pathway above. Does your product cause any hurdles or disruptions for stakeholders before or after use? This is important to think about and address in order to evaluate how you can introduce your technology without causing negative events upstream or downstream.

Defining Value in the Healthcare Ecosystem

Define the value that the technology will bring into the system. Does it improve outcomes? Provide higher quality care? Decrease costs? Save time? A framework for assessing value is through the Triple Aim. The Triple Aim was developed by the Institute for Healthcare Improvement and is used in assessing how a product or service will deliver high value in healthcare delivery systems. The three dimensions of the Triple Aim are:

- Improve experience (quality of care and patient satisfaction)
- Improve outcomes
- Reduce cost

As someone with a mission to introduce and sell a new product into the healthcare system, it is important that you understand how your product is positioned in addressing the dimensions of the Triple Aim. In order to do this, we ask you to consider the three dimensions of the Triple Aim and determine how you will demonstrate that your product delivers high value in healthcare.

You need to be able to express the value of your innovation to those who will be using it on a regular basis. Be transparent in the capabilities of your technology. Although there may be great positive value, it is also important to address any negatives. What is going on both upstream and downstream of where your technology will be placed? Are there any direct or indirect costs associated with the implementation? For example, is there training required for the clinician prior to using the device that will pull them away from clinical duties for a significant amount of time?

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SUMMARY AND ADDITIONAL RESOURCES

An implementation plan can be a very helpful, albeit complex, resource for your product's stakeholders. A great example, included in this module, is the Integrated Care Pathway for Total Joint Arthroplasty from the Institute for Healthcare Improvement (IHI) and Premier healthcare alliance, in that it takes a complicated care pathway and dissects it into current standards and best practices.

As you utilize the information you gather in positioning your technology for clinical adoption, be careful to use appropriate wording when describing your technology to a wider audience. Be transparent about the current developmental stage (i.e. waiting for FDA approval) and do not overstate the capabilities of the product, for example, that it is meant for a specific condition or population. Refer to the attached resource, TREAT Regulatory Module, to better understand claiming indications for use on a medical device. Only after the FDA approves use of the product for a particular indication can you market it as such.

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