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Custom Orthopaedic Oncology Implants: One Institution's Experience with Meeting Current IRB and FDA Requirements

BACKGROUND: Custom orthopaedic implants are often needed for patients with primary malignant bone tumors. In the last few decades, there has been an increased prevalence of limb salvage surgery, necessitating implants designed to fill large bone defects in patients of all ages and sizes with unique anatomy. Orthopaedic implants are not perfect. During a patient's lifetime, complex mechanical problems can develop requiring custom implants for revision surgeries under unique circumstances. In the current political climate, obtaining custom orthopaedic implants for orthopaedic oncology patients can be an arduous task involving submitting approval requests to the Institutional Review Board (IRB) and the Food and Drug Administration (FDA). There is great potential for the delay of a patient's surgery and unnecessary paperwork if the submission pathways are misunderstood or a protocol to streamline approval is not in place. The objective of this study was to review the existing FDA custom implant approval pathways and to determine how long it took to obtain approval for custom implants utilizing an institutional protocol designed to expedite the process.

METHODS: An institutional protocol for obtaining IRB and FDA approval for custom orthopaedic implants was established with the IRB at our institution in 2013. This protocol was approved by the IRB, such that new patients only require submission of a modification to the existing protocol with individualized patient information. During the two year period of 2013-2014, eight patients were retrospectively identified as having required custom implants for various orthopaedic oncology surgeries (e.g. primary tumor resection and reconstruction, prosthesis revision). The dates of request for IRB approval, request for FDA approval, and total time to surgery were recorded, along with the specific pathway utilized for FDA approval.

RESULTS: The average patient age was 12 years old (7-21 years old). Patients were diagnosed with either osteosarcoma or Ewing's sarcoma. Half of the implants were for primary resections with reconstruction, and half of the implants were for revision surgeries. The average time to IRB approval of a modification to the pre-approved protocol was 14 days (7-21 days). Average time to FDA approval after submission of the IRB approval to the manufacturer was 12.5 days (7-19 days). This compares favorably to the submission of an entirely new protocol, which is an arduous and time consuming process and at our institution typically requires approximately 35 days for approval. FDA approval was obtained for all implants as compassionate use requests in accordance with Section 561 of the Federal Food Drug and Cosmetic Act's expanded access provisions.

CONCLUSIONS: Establishment of an institutional protocol with pre-approval by the IRB can facilitate the otherwise time-consuming and complicated process of obtaining custom orthopaedic implants for orthopaedic oncology patients.