UNIVERSITAT POLITÈCNICA DE VALÈNCIA

An Economic analysis of digitalized and standardized workflows within the Operating room

Cumulative PhD

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1 Abstract

Digitalization in healthcare still lags compared to many other industries but offers the potential to cope with increasing challenges. This thesis examines the example of digital workflow management implemented in the surgical Operating Room (OR) and what the impact of digitalization on quality, efficiency and economics for hospital management could be.

The methodology for this research is based on a quantitative approach. First, an overview and analysis of the healthcare market and an extensive systematic literature review were carried out. It was focused on the efficiency and economic impact of standardization and digitalization of intraoperative processes in the OR. The findings provided the basis for the research questions around digital workflow-management-systems. Single-center hospital data on a digital workflow-management-system, Surgical Process Manager (SPM), has been retrospectively extracted and analyzed in orthopedics and general & visceral surgery (G&V) to fill identified research gaps. Additionally, provided patient data has been retrospectively used for economic calculations to conclude the main research question in G&V, focusing on obesity surgery.

The main findings of the thesis show that implementing digital workflow management systems, in the example of the SPM, improves efficiency and economics in obesity surgery. The odds ratio analysis to assess the impact on quality did not allow conclusions in orthopedics or obesity surgery. The cost-benefit calculation in obesity surgery showed cost savings of 318 € per patient, totaling 10,073€. This economic benefit was achieved by decreasing the length of stay (-1.2 days). For the first time, research provides evidence of the economic value of digitized and standardized processes in the OR in G&V. The results will facilitate investment decisions in digitization of hospital management and offer options to overcome the financial burden in the current healthcare market. Also, the findings provide in-depth details on specific cost structures, calculations, reimbursement, and how to effectively measure the financial impact on digital systems in the OR.

1 Resumen (Castellano)

La digitalización en la sanidad sigue poco desarrollada en comparación con muchos otros sectores, pero ofrece la posibilidad de hacer frente a retos cada vez mayores. A partir del caso de un sistema digital de gestión del flujo de trabajo implantado en el quirófano, esta tesis examina cuál podría ser el impacto de la digitalización en la calidad, la eficiencia y la economía de la gestión hospitalaria.

La metodología de investigación se basa en un enfoque cuantitativo. En primer lugar, se ha desarrollado una visión general y un análisis del mercado sanitario europeo, así como una amplia y sistemática revisión bibliográfica. Esta se ha enfocado en la eficiencia y el impacto económico de la estandarización y digitalización de los procesos intraoperatorios en el quirófano. Los resultados proporcionaron la base para derivar las preguntas de investigación en torno a los sistemas digitales de gestión del flujo de trabajo. Para cubrir las lagunas de investigación identificadas, se han obtenido y analizado de forma retrospectiva datos de un hospital, como estudio de caso, sobre un sistema digital de gestión del flujo de trabajo, Surgical Process Manager (SPM), en ortopedia y cirugía general. Los datos adicionales proporcionados por los pacientes, se han utilizado de forma retrospectiva para realizar cálculos económicos con el fin de responder a la pregunta principal de la investigación en cirugía general, centrándose en la cirugía de la obesidad.

Las principales conclusiones de la tesis muestran que la implantación de sistemas digitales de gestión del flujo de trabajo, como el SPM, mejora la eficiencia y la economía en la cirugía de la obesidad. El análisis de odds ratio (razón de oportunidades/probabilidades) para evaluar el impacto en la calidad no permitió extraer conclusiones ni en ortopedia ni en cirugía de la obesidad. El cálculo coste-beneficio en cirugía de la obesidad mostró un ahorro de costes de 318 euros por paciente, lo que supuso un total de 10.073 euros. Este beneficio económico se consiguió gracias a la disminución de la duración de la estancia (-1,2 días). Por primera vez, esta investigación aporta pruebas sobre el valor económico de los procesos digitalizados y estandarizados en el quirófano en cirugía general y ambulatoria. Los resultados facilitarán las decisiones de inversión en digitalización de la gestión hospitalaria y ofrecerán opciones para superar la carga económica en el mercado sanitario actual. Además, los resultados proporcionan detalles en profundidad sobre estructuras de costes específicas, cálculos, así como reembolsos y cómo medir eficazmente el impacto financiero en los sistemas digitales en el quirófano.

1 Resum (Catalan)

La digitalització de l'assistència sanitària encara està endarrerida en comparació amb moltes altres indústries, però ofereix el potencial per fer front als reptes creixents. Aquesta tesi examina sobre l'exemple d'un sistema de gestió de flux de treball digital, implementat al quiròfan quirúrgic (OR), quin podria ser l'impacte de la digitalització en la qualitat, l'eficiència i l'economia per a la gestió hospitalària.
La metodologia d'aquesta investigació es basa en un enfocament quantitatiu. En primer lloc, es va fer una visió general i anàlisi del mercat sanitari i una extensa revisió sistemàtica de la literatura. Es va centrar en l'eficiència i l'impacte econòmic de l'estandarditzación i la digitalització dels processos intraoperatoris al quiròfan. Les troballes van proporcionar la base per derivar les preguntes de recerca al voltant dels sistemes de gestió de flux de treball digitals. Per cobrir els buits de recerca identificats, s'han extret i analitzat retrospectivament dades d'hospitals d'un sol centre en un sistema de gestió de flux de treball digital, Surgical Process Manager (SPM), en ortopèdia i cirurgia general i visceral (G&V). S'han utilitzat retrospectivament dades addicionals dels pacients per a càlculs econòmics per concloure la pregunta principal de recerca en G&V amb un enfocament en la cirurgia de l'obesitat.

Les principals conclusions de la tesi mostren que la implementació de sistemes digitals de gestió de flux de treball, a partir de l'exemple de l'SPM, millora l'eficiència i l'economia en la cirurgia de l'obesitat. L'anàlisi d'odds ratio per avaluar l'impacte en la qualitat no va permetre treure conclusions ni en ortopèdia ni en cirurgia de l'obesitat. El càlcul cost-benefici en cirurgia de l'obesitat va mostrar un estalvi de costos de 318 € per pacient, que va ascendir a 10.073 €. Aquest benefici econòmic es va aconseguir mitjançant la disminució de la durada de l'estada (-1,2 dies). Per primera vegada la investigació proporciona evidència sobre el valor econòmic dels processos digitalitzats i estandarditzats a la sala d'operacions en G&V. Els resultats facilitaran les decisions d'inversió en la digitalització de la gestió hospitalària i oferiran opcions per superar la càrrega econòmica del mercat sanitari actual. A més, les troballes proporcionen detalls detallats sobre estructures de costos específiques, càlculs, així com el reemborsament i com mesurar eficaçment l'impacte financer en els sistemes digitals de l'OR.

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Content

3 Introduction

In many industries, digitization and efficiency optimization have rapidly evolved. In healthcare, many stakeholders have not yet adopted IT solutions or efficiency management concepts to their full potential. The reasons are manifold, but some major ones are challenges with data privacy and technological infrastructure, lack of professional expertise, sufficient investment resources and missing evidence of its economic value. The need to invest in or adopt new concepts has risen since the financial pressure has increased amongst all stakeholders, particularly hospitals, payors, and healthcare companies over the past years. Much attention is drawn towards hospitals' operating rooms (OR) because 40% of the total hospital costs occur in this area. Improvements in efficiency and quality in the OR can significantly reduce the economic pressure on hospitals and other stakeholders. Literature has shown that different standardized methods of intraoperative processes led to efficiency improvements, which resulted in significant cost reductions. While efficiency improved, quality was maintained.

The Thesis begins by providing an overview and analysis of the status of the healthcare market and the level of digitalization. It also gives recommendations to medical companies regarding selected marketing controlling instruments and investments into digitalization on how to overcome upcoming challenges. Following the perspective of medical companies, a systematic literature review has been carried out to identify relevant research gaps in standardized and digitized intraoperative surgical procedures within hospitals. This review focused on this area as hospitals and payors have recognized it as one of the most critical levers to overcome the economic pressure. Based on the findings, a clinical research design has been developed with a German hospital to fill identified gaps in the standardization and digitization of intraoperative surgical processes.

4 Methodology

For every thesis, a research approach needs to be selected. For this research the deductive approach was chosen, which is based on a developed theory and hypothesis, followed by the design of a research strategy to test the hypothesis.

The thesis consists of three parts: a description of the healthcare market and theoretical marketing controlling concepts. Combined with practical examples, it provided an overarching overview and laid out the need for concept adjustments and potential investments into digitization.

Second, a systematic literature review (SLR) according to the process of Kitchenham and Charters was carried out. It consisted of three phases: planning, conducting, and reporting the study. For the planning phase, a qualitative research checklist for SLRs has been chosen to determine qualitative relevant publications. Following the planning process strategy, search criteria and terms were defined and applied during the conduction phase. Several search combinations and pre-determined quality conditions during the SLR led to the exclusion and inclusion of relevant literature. In the last step, the results of the conducted SLR between October 2020 and March 2021 and broadened for digitalization in March 2023 were reported.

The third part of the thesis consists of retrospective case control-trials. The collected data is being analyzed to test the hypothesis and fill the identified research gaps. The research strategy was designed and applied in orthopedics (knee joint replacements) and visceral surgery (Roux-en-Y Gastric Bypass), fulfilling the need for more advanced surgical procedures. In both single-center trials, the digital workflow-management-system, “Surgical Procedure Manager” (SPM), has been implemented, analyzed, and compared to non-SPM patient groups. In both research designs, propensity score matching was applied within the statistical analysis to verify the hypotheses. The aim of those trials was to investigate whether digital-support systems, in the example of SPM, impact the efficiency and quality of intraoperative surgical workflows. An economic analysis (cost-benefit) of Roux-en-Y Gastric Bypasses without and with the SPM was carried out to close the most essential research gap. This analysis demonstrated the financial impact of digitized and standardized intraoperative surgical workflows for hospitals and the healthcare market.

5 Articles

5.1 Article: Marketing-Controlling in Unternehmen der Medizintechnik

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Abstract:

Medical technology companies are facing new and, above all, significant challenges due to regulatory and legal changes and increasing digitization. To meet these requirements, the function of marketing controlling is becoming more and more critical. However, companies are only making insufficient investments urgently needed to ensure future viability.

First, a secondary analysis of the status quo of marketing controlling in the German healthcare market is carried out. Based on this, it is shown how medical technology companies can use selected marketing controlling instruments to add value. Against the background of remaining competitive in the future, the influence of digitization and big data is presented.

Zusammenfassung:

Medizintechnik-Unternehmen stehen aufgrund von regulatorischen und rechtlichen Veränderungen und der zunehmenden Digitalisierung vor neuen und vor allem großen Herausforderungen. Um diesen Anforderungen gerecht zu werden, gewinnt die Funktion des Marketing-Controllings immer mehr an Bedeutung. Dringend benötigte Investitionen zur Sicherstellung der Zukunftsfähigkeit werden von den Unternehmen aktuell jedoch nur unzureichend getätigt.

Zunächst erfolgt eine Sekundäranalyse des Status Quo zum Marketing-Controlling im deutschen Gesundheitsmarkt. Darauf aufbauend wird dargestellt, wie ausgewählte Marketing-Controlling- Instrumente von Medizintechnik-Unternehmen wertschöpfend angewandt werden können. Vor dem Hintergrund, auch zukünftig wettbewerbsfähig zu bleiben, wird abschließend der Einfluss von Digitalisierung und Big Data dargestellt.

1. Einführung

Die Gesundheitswirtschaft ist mit ca. 7,5 Millionen Erwerbstätigen einer der wichtigsten Wirtschaftszweige in Deutschland. Knapp 17% der 44,5 Millionen Erwerbstätigen arbeiten in der Gesundheitsbranche. Die Anzahl der Arbeitsplätze steigt kontinuierlich seit den letzten 10 Jahren und die Branche gilt mit 1,2 Millionen neu geschaffenen Stellen seit 2010 aktuell als einer der führenden Wachstumsmotoren in Deutschland. Insgesamt werden hier 372 Milliarden Euro p.a. erwirtschaftet, was in etwa 12,1 Prozent des gesamten Bruttoinlandsproduktes (BIP) entspricht. In Bezug auf die Bruttowertschöpfung wird somit jeder achte Euro in der Gesundheitswirtschaft generiert. Das Wachstum der Bruttowertschöpfung beträgt im Gesundheitswesen 4,1 % p.a. und liegt damit 0,8% über dem derzeitigen durchschnittlichen Wachstum der Gesamtwirtschaft. Dadurch, dass die Gesundheitsbranche einen Großteil ihrer Vorleistungen aus anderen Wirtschaftsbereichen,

wie dem produzierenden Gewerbe (zu circa 25%) bezieht, stärkt sie maßgeblich den Wirtschaftsstandort Deutschland (vgl. BMWi 2020, S.6 f.; BVMed 2020, S. 3 f.).

Die Gesundheitswirtschaft ist in Deutschland in drei Bereiche unterteilbar: „Medizinische Versorgung“, „industrielle Gesundheitswirtschaft“ und „weitere Teilbereiche“. Die Medizinische Versorgung erwirtschaftet mit knapp 200 Milliarden Euro mehr als die Hälfte der gesamten Bruttowertschöpfung (vgl. BMWi 2020, S.7). Neben Humanarzneimitteln gehören die Medizintechnikprodukte zu den Kernbereichen in der Kategorie der industriellen Gesundheitswirtschaft. Insgesamt sichern diese beiden Kernbereiche ca. 490.000 Arbeitsplätze in Deutschland (vgl. BMWi 2020) und erwirtschaften 81,2 Milliarden Euro. Die industrielle Gesundheitsbranche erwirtschaftet so 21,8% der Bruttowertschöpfung der gesamten Gesundheitswirtschaft. Im Bereich der Medizintechnik und -produkte Branche arbeiten ca. 200.000 Beschäftigte in Deutschland. Der Gesamtumsatz der produzierenden Unternehmen mit mehr als 20 Mitarbeitern belief sich in 2019 auf 32,4 Milliarden Euro. Das ist im Gegensatz zum Vorjahr ein Plus von 10,4%. Der Inlandsumsatz dieser Unternehmen lag bei 11,5 Milliarden, wodurch das Wachstum mit 9,5% etwas niedriger ausfiel als beim Auslandsumsatz (vgl. BVMed 2020, S. 5).

Auch wenn die EBIT-Margen in der Medizintechnik überdurchschnittlich sind, steht die Branche derzeit vor einigen Herausforderungen. Die rechtlichen und regulatorischen Rahmenbedingungen zur Markteinführung und -überwachung waren über 25 Jahre durch die Medical Device Directive (MDD) und das Medizinproduktegesetz (MPG) vorgegeben. Durch die für 2021 geplante Einführung einer neuen europäischen Verordnung, der Medical Device Regulation (MDR), werden einige Veränderungen in Kraft treten. Diese führen zum Beispiel zu neuen Klassifizierungen und Bewertungsverfahren von Produktgruppen. Weitere Änderungen sind erhöhte Anforderungen an klinische Bewertungen und die Erstellung von klinischen Daten sowie Risiko- als auch Qualitätsmanagementsysteme. Darüber hinaus wird es zu einer neuen Regelung bei der Überwachung von Medizinprodukten nach deren Markteinführung kommen (vgl. Dispan 2020, S. 36).

Diese und weitere Veränderungen der MDR haben zum Ziel, die Qualität der Medizinprodukte zu steigern und schlussendlich die Patientensicherheit zu erhöhen. Darüber hinaus ist es ein erklärtes Ziel, die medizinische Evidenz über klinische Studien sowie die Nachverfolgbarkeit der Medizinprodukte zu erhöhen (vgl. Dispan 2020, S. 36). Seitens der Hersteller werden allerdings Kritikpunkte an der neuen Verordnung laut. Nach einer Umfrage bei 320 Herstellern gehen 79% der befragten Unternehmen von stark erschwerten Bedingungen aus, innovative Produkte zukünftig auf dem Markt einzuführen. Knapp drei von vier Unternehmen rechnen mit steigenden Kosten beim Marktzugang und etwa die Hälfte der Hersteller kalkuliert mit einer Verschlankung der eigenen Produktlinien (vgl. DIHK 2019, S.7). Damit einhergehend wird der Druck durch die neue MDR insbesondere bei kleinen und mittelständischen Unternehmen steigen. Insgesamt wird erwartet, dass ca. 30% der Medizinprodukte vom Markt verschwinden und dadurch Versorgungsengpässe entstehen könnten (vgl. BVMed 2020, S. 12).

Neben den neuen rechtlichen und regulatorischen Rahmenbedingungen in der Medizintechnik, sind die Finanzierungs- und Investitionsmöglichkeiten der Leistungserbringer (z. B. Städtische Krankenhäuser) deutlich zurückgegangen. In Deutschland existiert ein duales Finanzierungssystem, um die Versorgungsleistungen abzudecken. Die gesetzlichen und privaten Krankenkassen tragen in diesem Modell die betrieblichen Kosten der Leistungserbringer. Darunter fallen zum Beispiel Kosten für medizinische Leistungen oder benötigtes Fachpersonal (Ärzte u.a.) (vgl. Ärzteblatt 2019). Über DRG's (Diagnosis-Related-Group), die Patientenfälle mit ähnlichen Kosten zusammenfassen, werden die Krankenhausleistungen dokumentiert und abgerechnet. In den letzten Jahren wurden im Zuge der Krankenhausstrukturreform etliche Veränderungen eingeführt. Unter anderem sollte durch die Reform die Qualität der Krankenhausversorgung erhöht, die Mengensteuerung in der stationären Versorgung neu ausgerichtet und die Kalkulation der Entgeltsysteme im Krankenhaus durch eine verbesserte Grundlage repräsentativer dargestellt werden (vgl. BMG 2017). Außerdem wurde eine Änderung in der Kalkulationsmethode vorgenommen mit der Folge, dass die Vergütung von sachkostenintensiven Leistungen abgesenkt wurde. Dies führte bei Leistungserbringern, wie den Krankenhäusern, die auf bestimmte Fachdisziplinen spezialisiert sind, zu einer neuen preislichen Drucksituation, die im Endeffekt mit beteiligten Interessensgruppen, wie etwa Herstellern von Gelenkprothesen, gelöst werden musste.

Die zweite Säule des dualen Finanzierungssystems betrifft alle anfallenden Investitionen. Diese Investitionsbudgets werden von den einzelnen Bundesländern verantwortet. Für Investitionen wie Instandhaltungen, Modernisierungen oder technische Ausstattungen werden in Deutschland ca. sechs Milliarden Euro pro Jahr benötigt. Derzeit werden aber nur etwa die Hälfte der benötigten Investitionsmittel zur Verfügung gestellt (vgl. Ärzteblatt 2019). Durch die Verknappung an Investitionsmitteln suchen Leistungserbringer verstärkt nach Möglichkeiten, laufende Kosten zu senken. Beispielsweise werden über große Einkaufsgemeinschaften (EKG) Sachkosten reduziert. Ebenso führt die kontinuierliche Optimierung von Arbeitsabläufen entlang des Patientenpfades innerhalb eines Krankenhauses zu effizienteren und damit zumeist auch kostengünstigeren Prozessen. Auf Medizintechnik-Unternehmen bezogen führen diese Maßnahmen der Leistungserbringer, neben anderen Veränderungen, zu einem erhöhten Preis- und Wettbewerbsdruck.

Neue Lösungsansätze, um den veränderten Marktbedingungen entgegenzutreten, bietet die Digitalisierung im Gesundheitswesen. Gemessen am Wirtschaftsindex gehört das Gesundheitswesen dabei mit 36 von 100 Punkten zu den Bereichen, die noch stark unterdurchschnittlich digitalisiert sind (Durchschnitt liegt bei 49 Punkten) (vgl. BMWi 2020, S. 34).

2. Marketing-Controlling in Medizintechnik-Unternehmen

2.1. Überblick

Marketing ist im Gesundheitswesen in allen Bereichen entlang des Versorgungsprozesses anwendbar. Ein solcher Prozess kann dazu in drei Säulen unterteilt werden: Prävention, Diagnose & Therapie sowie Nachsorge (vgl. Meffert und Wölde-Lübke 2017, S. 214). In jeder Säule gibt es primäre Interessengruppen, die sich auf bestimmte Kunden oder Geschäftspartner konzentrieren. Wie in der Marktbeschreibung dargestellt, bestimmen entlang des Versorgungsprozesses gewisse staatliche Regulierungen den Rahmen. Zum Beispiel werden die Versorgungsleistung und -vergütung der einzelnen Therapieformen (DRG) stark reguliert. Diese Regulierungen sind notwendig, weil z. B. viele Informationen über den Bedarf und den Nutzen in der Versorgung mangelhaft oder verzerrt sind. Dies wird am Beispiel der Bewertung von medizinischen Leistungen durch einen Patienten deutlich. Oftmals über- oder unterschätzen Patienten die medizinische Leistung während des Krankenhausaufenthaltes aufgrund des fehlenden medizinischen Verständnisses oder lückenhafter Bereitstellung von Informationen seitens der Leistungserbringer während der Therapie. Darüber hinaus werden Daten zur Patientenzufriedenheit und zur Versorgungsqualität nur teilweise von Krankenhäusern oder deren individuellen Versorgungsbereichen gesammelt, verwertet und mit anderen Interessensgruppen entlang des Versorgungsprozesses geteilt.

Medizintechnik- oder Pharmaunternehmen können sich mit Ihren Marketingaktivitäten in jeder der drei benannten Säulen wiederfinden. Medizintechnik-Unternehmen, die Produkte oder Dienstleistungen etwa für chirurgische Eingriffe herstellen und anbieten, fokussieren ihre Marketingaktivitäten hauptsächlich auf den Bereich der Diagnose & Therapie. Ihre Zielgruppen werden definiert durch die Akteure und Entscheidungsträger innerhalb des Versorgungsprozesses. Ihre primäre Zielgruppe ist in diesem Fall die Ärzte, die direkt am Prozess beteiligt sind. Durch die sich stetig verändernden Marktbedingungen, mit einem erhöhten Fokus auf die Versorgungsqualität und Wirtschaftlichkeit, sind weitere Zielgruppen wie Einkäufer oder Geschäftsführer in den Fokus gerückt; diese sind ebenfalls zu berücksichtigen.

In diesem Zusammenhang ist die Anwendung des Marketing-Mixes der 4 P's für Medizintechnik-Hersteller nur noch bedingt empfehlenswert. Ein neuer Ansatz wie SAVE trägt den veränderten Anfordernissen und Marktbedingungen Rechnung. Bei rund 400.000 Medizinprodukten von diversen Herstellern im deutschen Markt für Diagnostik, Implantate, chirurgische Instrumente und OP-Material ist es wichtig für Kunden, technologische Vorteile eindeutig zu erkennen oder Funktionen auseinander zu halten, insbesondere vor dem Hintergrund, dass sich der Produktlebenszyklus immer weiter verkürzt. Aufgrund des vielfältigen Angebotes an Produkten und Dienstleistungen werden zwingende Bedürfnisse seitens der agierenden Akteure in diesem Versorgungsprozess zwar erkannt, können aber selten mit Herstellern und Produkten in einen Zusammenhang gebracht werden. Durch gezielte Angebote für Kundenbedürfnisse ist diese Herausforderung allerdings zu

bewältigen. Im Gegensatz zu anderen Branchen muss ein Medizintechnik-Unternehmen bestimmte Anforderungen erfüllen, bevor das Produkt im Markt eingeführt und mit Nutzenwerten beworben werden kann. Zu diesen Anforderungen gehören Risikoanalyse und -bewertung zum Nachweis der Sicherheit, die Durchführung einer klinischen Bewertung bzw. Prüfung zum Nachweis der Leistungsfähigkeit und Wirksamkeit sowie ein umfassendes Qualitätsmanagementsystem (vgl. BVMed 2020, S. 17). Nicht ohne Grund werden schon während der Produktentwicklung viele direkte Anwender miteinbezogen. Es ist entscheidend, frühzeitig zu evaluieren, ob und wie das neue Produkt die Bedürfnisse im Markt befriedigen kann und ob der Nutzen im Verhältnis zum erzielbaren Preis im Markt ausreichend ist.

Der Begriff Access enthält die optimale Verfügbarkeit der Produkte und Informationen über alle Kanäle. Im Gegensatz zur Produktverfügbarkeit aus anderen Industrien sind Medizinprodukte nur teilweise online erhältlich. Viele Produkte, wie OP-Material oder einfache medizinische Instrumente, können über Händler oder Hersteller bezogen werden. Komplexere Produkte werden weiterhin primär über klassische Vertriebskanäle, wie den eines Außendienstes, verkauft. Nichtsdestotrotz ist es für Unternehmen in der Medizintechnik elementar, ihre Produkte und die benötigten Informationen über verschiedene Kanäle, wie online, über Kundensupport (telefonisch oder digital), Social Media oder das Vertriebsteam anzubieten.

In dem derzeitigen Umfeld mit vielen Wettbewerbern und wirtschaftlichen Herausforderungen für die Krankenhäuser und privaten Krankenhausgesellschaften wird die Positionierung eines Produktes aufgrund der Produktionskosten oder der Wettbewerbspreise immer weniger zum mittel- bis langfristigen Erfolg führen. Vielmehr sollte über eine klare Kommunikationsstrategie der Mehrwert des Produktes für den Kunden dargestellt werden. Dieser kann sich in verschiedenen Formen wiederfinden, wie z. B. in erhöhter Patienten-Sicherheit oder in effizienteren und effektiveren Arbeitsabläufen für das medizinische Personal.

Als letzte Maßnahme des SAVE-Marketing-Modelles überzeugen Medizintechnik-Unternehmen über Inbound Marketing ihre Kunden. Dabei wird, im Gegensatz zur Werbung oder Öffentlichkeitsarbeit, die den Kunden nicht direkt miteinbezieht, ein gesteigerter Wert auf Aufklärung und Beratung gelegt. Bei einer solchen sogenannten Education ist es bedeutsam, während und nach dem Kaufprozess eine partnerschaftliche Kundenbeziehung aufzubauen. Das erweckt Vertrauen in den Prozess beim Kunden und bietet dem Unternehmen die Möglichkeit, weiterhin zielgerichtet Produkte den individuellen Kundenbedürfnissen anzupassen.

Das Controlling im Gesundheitswesen bezieht sich beim Bereitstellen von entscheidungsrelevanten Informationen primär auf Wirksamkeit und Wirtschaftlichkeit. Darüber hinaus spielen neben Produkten auch Dienstleistungen eine entscheidende Rolle im Gesundheitswesen, wodurch einige Besonderheiten des Dienstleistungscontrollings zu beachten sind. Beispiele für relevante Faktoren, die zu berücksichtigen sind, sind etwa:

- Einbeziehung externer Variablen: Bei der Herstellung der Dienstleistung ist immer der Leistungsempfänger, in diesem Fall der Patient, beteiligt. Das kann zu Planungsunsicherheiten oder Standardisierungsproblemen führen.
- Harte und weiche Kennzahlen: Neben harten Kennzahlen, wie Bettenauslastung, Schnitt-Naht-Zeiten im OP-Saal oder Anzahl an Prozeduren, spielen weiche Kennzahlen, wie Patienten- oder Anwenderzufriedenheit, Vertrauen oder Lebensqualität, eine wichtige Rolle. Die weichen Kennzahlen sind in der Regel schwierig zu messen.
- Vorleistung der Leistungserbringer: In der Regel müssen Krankenhäuser Kapazitäten wie Personal, Räume und Equipment vorhalten. Sollte die Anzahl an Patienten nicht für eine 100 prozentige Auslastung und Kostendeckung reichen, besteht das Risiko eines Preiswettbewerbes, der zur Insolvenz führen kann (vgl. Tiemann und Matusiewicz 2017, S. 274 f.).

Neben diesen genannten Faktoren existieren noch eine Reihe weiterer spezifische Gegebenheiten bei der Planung, Kontrolle und dem Berichtswesen des Controllers im Gesundheitswesen. Aufgrund der geringen Relevanz zu den nachfolgenden Themenblöcken in der Medizintechnik wird auf diese im Folgenden nicht näher eingegangen.

2.2. Ausgewählte Instrumente

Das Marketing-Controlling umfasst eine große Spannbreite an Aufgaben innerhalb des Unternehmens. Um anschließend gezielt auf einzelne Aspekte und Instrumente des Marketing-Controllings in der Medizintechnik einzugehen, wird zunächst eine empirische Studie der Universität St. Gallen herangezogen (vgl. Reinecke 2016).

Für die empirische Studie wurde ein standardisierter Online-Fragebogen mit einer Likert Skalierung von 1 (trifft gar nicht zu) bis 7 (trifft voll zu) genutzt. Die Studie wurde im deutschsprachigen Raum, hauptsächlich in der Schweiz, durchgeführt. Von 4226 kontaktierten Führungskräften haben 388 den Fragebogen beantwortet. Fast 2/3 der Befragten (64%) waren in einer leitenden Funktion des Unternehmens, als Geschäftsführer oder Aufsichts- bzw. Verwaltungsrat tätig. Die restlichen Befragten setzten sich aus Marketing- oder Vertriebsleitern sowie Controllern zusammen. 34% der teilnehmenden Unternehmen hatten mehr als 500 Mitarbeiter, 27% zwischen 50 und 499 Mitarbeiter und 39% weniger als 50 Mitarbeiter (vgl. Reinecke 2016, S. 202).

Eine Erkenntnis der Studie ist, dass fast kein Unternehmen sehr zufrieden mit seinem Marketing-Controlling war. Mit einem Zufriedenheitswert der Unternehmensleitung von 3,57 ist dieser mit mäßig zu beschreiben. Insgesamt wurde angegeben, dass die größten Herausforderungen für das Marketing-Controlling zum einen in der „Messbarkeit des Marketings“ und zum anderen beim Aufbau einer „Informations- und Datenbasis im Marketing“ liegen. Allerdings merkte Reinicke (2016, S. 205) in der Analyse an, dass gerade diese

Herausforderungen vom Marketingmanagement selbst positiv beeinflusst werden können. Um die Messbarkeit des Marketings zu verbessern, sind konkrete Zielsetzungen mit operationalisierbaren Kennzahlen zielführend. Die zweite Herausforderung ist durch Investments in Marktforschung zu lösen. Vor diesem Hintergrund ist nicht die Messbarkeit die größte Herausforderung für das Marketing-Controlling, sondern vielmehr die eindeutige Zuordnung von Ursachen und Wirkungen. Um die speziellen Wirkungsleistungen der einzelnen Marketing-Instrumente besser zuzuordnen, sind detaillierte Zwischenziele, wie Bekanntheitsgrad, Besuchs- und Kontaktfrequenzen oder Absichten, zu definieren (vgl. Reinecke 2016, S. 205 f.).

Eine wichtige Komponente in der Funktion des Marketing-Controllings ist die Budgetierung. 56% der Unternehmen gaben an, als Grundlage für die Marketingbudgetierung das Budget des Vorjahres heranzuziehen und 52% der Budgetierung wird auf Basis von Managementerfahrung bzw. -intuition entschieden. In Kombination mit dem angegebenen Einsparungspotential von knapp 15% im Marketingbereich sind über zielorientierte Methoden in der Marketingbudgetierung, die über Umsatz und Absatz hinausgehen, Optimierungsmöglichkeiten vorhanden (vgl. Reinecke 2016, S. 207).

Marketing-Controlling Instrumente lassen sich in strategische und operative Instrumente unterteilen. Einige Beispiele an Marketing-Controlling Instrumenten sind in Abbildung 1 dargestellt.

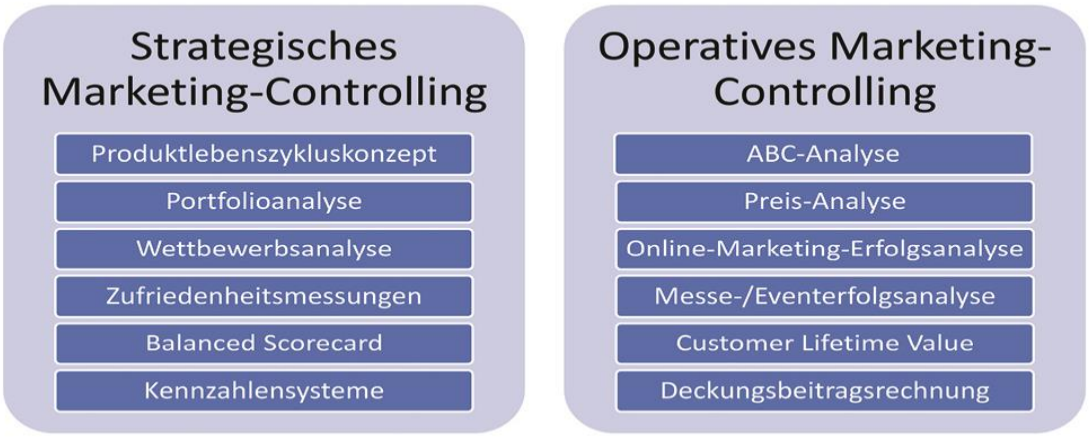

Abb. 1: Beispiele von strategischen und operativen Marketing-Controlling Instrumenten (Quelle: Eigene Darstellung in Anlehnung an Halfmann 2018 und Reinecke 2016).

Laut Reinecke (2016, S. 213) wurde von den erfolgreichsten Unternehmen (Top 25%) besonders Wert auf strategische Marketing-Controlling Instrumente, wie Zufriedenheitsmessungen (Kunden und Mitarbeiter), Frühwarnsysteme, Positionierungsstudien, Markenaudits und Balanced Scorecards gelegt. Insgesamt wurde angegeben, dass am häufigsten Konkurrenz- / Branchenanalysen, Zufriedenheitsbewertungen und Kennzahlensysteme von Unternehmen eingesetzt werden.

Bei den operativen Marketing-Controlling Instrumenten haben die Befragten am häufigsten den Einsatz von Preis- und Verkaufserfolgsanalysen sowie von Produkt- und Servicequalitätsanalysen angegeben. Bei den Instrumenten des Marketing-Accountings werden regelmäßig altbewährte Instrumente, wie Budgetanalysen, Deckungsbeitragsrechnungen (Produkte / Projekte) und Investitionsanalysen eingesetzt. Deckungsbeitragsrechnungen, orientiert am Kunden oder am Customer-Lifetime-Value, finden dagegen nur unregelmäßig bis selten statt. Die erfolgreichsten Unternehmen legen bei den operativen Instrumenten besonderen Wert auf intensives Kommunikationscontrolling (insbesondere Pre- und Posttests) sowie auf Optimierung des Media-Mixes sowie Sponsoring-Erfolgsanalysen (vgl. Reinecke 2016, S. 214).

Bei der Unterteilung in erfolgreiche und -lose Unternehmen werden die vier priorisierten Dimensionen (finanzwirtschaftliche, markt- und kundenorientierte, mitarbeiter- und prozessorientierte, innovationsorientierte Ziele) der Balanced Scorecard und die damit verbundene Ziel-Erreichung herangezogen (vgl. Reinecke 2016, S. 209). Zwischen dem Instrumenteneinsatz und dem Erfolg muss allerdings laut Reinecke kein Ursache- / Wirkungszusammenhang bestehen. (vgl. Reinecke 2016, S. 217).

Zusammenfassend geben die Ergebnisse der empirischen Studie Aufschluss über den Status des Marketing-Controllings in der betriebswirtschaftlichen Praxis. Einerseits ist der hohe Bedarf nach der Sicherstellung und Messbarkeit von Effektivität sowie Effizienz des Marketings vorhanden, andererseits stehen dem nicht ausreichende Implementierungen von geeigneten strategischen und operativen Instrumenten gegenüber, vor allem der Instrumente, die zur Optimierung der Marketingführungsprozesse und -Maßnahmen führen.

Nachfolgend wird auf die strategischen Instrumente SWOT-Analyse und Kundenzufriedenheitsbewertung sowie auf das operative Controlling-Instrument der Sponsoring-Erfolgsanalyse für den Einsatz in Medizintechnik-Unternehmen näher eingegangen.

SWOT-Analyse

Zur Durchführung einer Wettbewerbs- oder Situationsanalyse wird vom Marketing-Controlling seit langem die SWOT-Analyse eingesetzt. Diese beinhaltet die internen Stärken (Strengths) und Schwächen (Weaknesses) der Unternehmens-, Abteilungs- oder Produktgruppen. Demgegenüber steht die externe Analyse. Durch die Marktgegebenheiten bestehen Chancen (Opportunities) und Risiken (Threats), die von außen definiert und größtenteils nicht beeinflussbar sind. Die Erstellung einer SWOT-Analyse verlangt nach gründlicher Marktforschung mit belegbarem Zahlenmaterial (vgl. Halfmann 2018, S. 39).

Als fiktives Beispiel für den Einsatz der SWOT-Analyse dient im Folgenden das mittelständische Unternehmen Treat Medical, das wiederverwendbare chirurgische Fasszangen herstellt und vertreibt. Das Beispiel basiert auf realen Daten.

Ausgangslage: Der Hersteller beschäftigt aktuell 160 Mitarbeiter und ist mit dem Vertrieb seiner Produkte seit neun Jahren in der Medizintechnik-Branche tätig. Der Markteintritt erfolgte unter MDD-Bedingungen. Die Produktion der Instrumente befindet sich in Deutschland und wurde im Laufe der Jahre voll automatisiert. Darüber hinaus wurden vor vier Jahren erfolgreich Just-In-Time- Systeme eingeführt. Investitionen wurden in den letzten Jahren vorwiegend für kontinuierliche Optimierungen der Lieferketten getätigt, Investitionen in digitale Tools, wie CRM-Systeme oder soziale Netzwerke sowie R&D, wurden dagegen nicht getätigt. Mitarbeiterfortbildungen werden regelmäßig vorgenommen; ebenso werden kontinuierlich Kundenzufriedenheitsbewertungen durchgeführt.

Aktuelle Entwicklung: Umsatz- bzw. Marktanteilverluste von 17% gegenüber dem Vorjahr haben das Top-Management vor fünf Monaten dazu bewogen, eine ABC-Analyse durchzuführen. Als Folge wurde eine neue Kundensegmentierung vorgenommen und dementsprechend die Organisationsstruktur verändert. Durch die gezielte Ausrichtung auf A- und B-Kunden wurde das Außendienst-Team um 25% reduziert. In Abbildung 2 sind exemplarisch einige Punkte der vier Kategorien aufgeführt (vgl. Abb. 2).

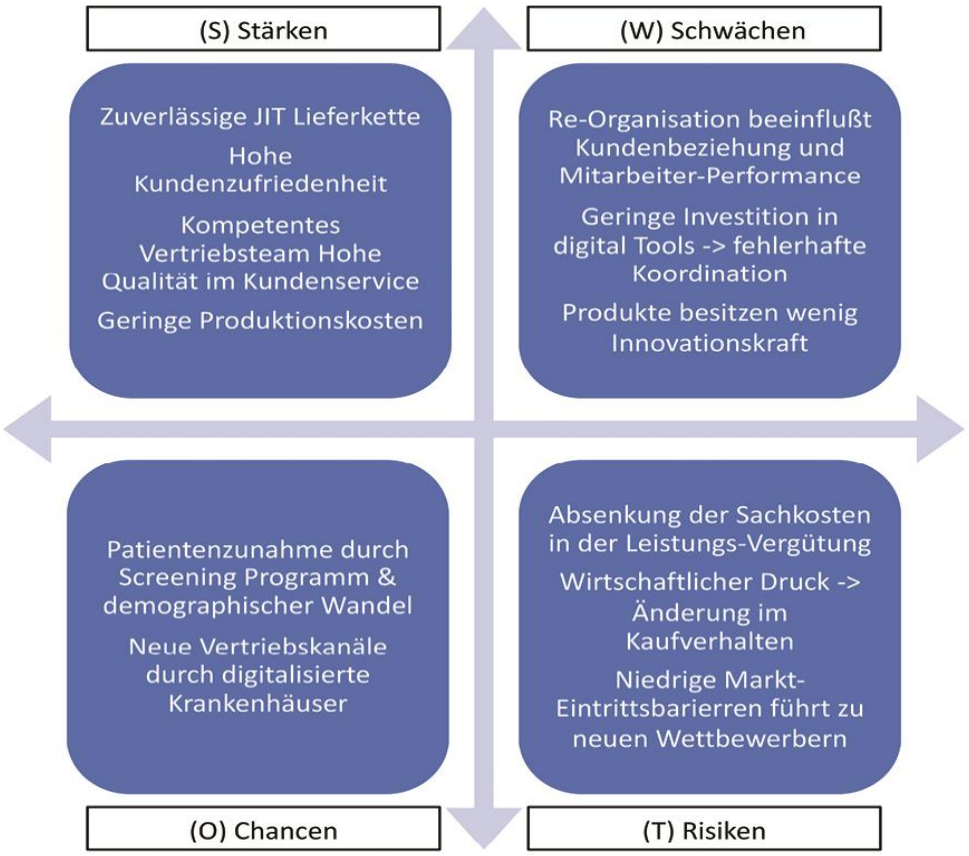

Abb. 2: Beispiel einer SWOT-Analyse (Quelle: Eigene Darstellung)

Während eines einberufenen Management-Workshops bei Treat Medical wurde eine SWOT-Analyse, mittels Erkenntnisse der Mitarbeiter und vom Marketing-Controlling bereitgestellten Daten, erarbeitet. Die getätigten Investitionen in die vollautomatisierte Produktion und JIT-Systeme wurden als Stärken erkannt. Durch weniger manuelle Produktionsschritte konnten Fehlerquellen behoben, Produktionszeiten verkürzt und die Qualität gesteigert werden. Diese Optimierungen resultieren für das Unternehmen in geringeren Produktionskosten und relativ hohen Margen. Aus den regelmäßigen Kundenzufriedenheitsumfragen konnte zudem ermittelt werden, dass die hohe Qualität der Produkte, die kontinuierlich geschulten Außendienstmitarbeiter und die JIT-Belieferung zu konstant hohen Zufriedenheitswerten führten.

Umstrukturierungen in der Vertriebsorganisation führen im Change-Prozess zu unterschiedlichen Performance-Phasen der Mitarbeiter bis der Wandel komplett integriert ist (vgl. Streich 1997). Der mit dem Change-Prozess einhergehende Wechsel der Kundenbetreuung führte beim Unternehmen Treat Medical zu einer Kundenfluktuation von 22%. Die geringen Investitionen in Produktentwicklung und damit fehlenden zukunftsträchtigen Produkten wurden vom Management als Schwäche identifiziert. Zusätzlich entstanden Informationslücken von Kundeninteraktionen auf Grund eines fehlenden CRM-Systems. Das führte zu unkoordinierten Anfragen beim Kunden vom Customer Service und den neuen Außendienstmitarbeitern bei Treat Medical.

Chancen durch das externe Umfeld wurden vom Management von Treat Medical wie folgt definiert: Ein neu eingeführtes Screening-Programm zur Früherkennung von Lungenkarzinomen hat zu einem Anstieg in der Patientenversorgung geführt. Das Unternehmen hat folglich die Möglichkeit zur Erweiterung von Marktanteilen erkannt und rechnet mit einer Steigerung des Umsatzpotentials von 14%. Zusätzlich ergeben sich durch die ansteigende Digitalisierung der Krankenhäuser für Treat Medical Optionen, über eine Online-Plattform neue Kunden zu erreichen und gegebenenfalls dort die Produkte günstiger (ohne Außendienstmitarbeiter) zu vertreiben.

Als letzte Säule der SWOT-Analyse hat Treat Medical im Workshop die Risiken betrachtet. In diesem Fall hat die Krankenhausstrukturreform zu Verschiebungen in den DRG’s sowie erschwerten Bedingungen der Fallzahlsteigerung geführt. Die Analyse hat ergeben, dass die Sachkosten in den relevanten Therapiebereichen um 36% reduziert wurden. Folglich erwartet das Unternehmen härtere Preisverhandlungen mit den Leistungserbringern und gleichzeitig niedrigere Wettbewerbspreise. Als ein weiteres aktuelles Risiko wurden die niedrigen Markteintrittsbarrieren eingestuft. Dadurch konnten innerhalb der letzten Monate bereits vier neue Anbieter für chirurgische Fasszangen im Markt verzeichnet werden.

Das beschriebene Beispiel der SWOT-Analyse deckt nicht das gesamte Spektrum ab und erfordert bei gezielter Anwendung eine erweiterte Betrachtung. Allerdings bietet dieses Instrument dem Controlling über tiefgreifende Analysen eine Grundlage zur Informationsbeschaffung und -aufbereitung. Die SWOT-Analyse hat allerdings auch Schwächen. So bietet die Analyse zwar Raum für Interpretationen, gibt aber keine direkten

Handlungsempfehlungen (vgl. Grunewald und Hempelmann 2017). Um der Kritik entgegenzutreten, ist die SWOT-Analyse idealerweise in Kombination mit anderen Instrumenten zu verwenden. Ein ergänzendes Instrument zur SWOT-Analyse ist die Wettbewerbsanalyse, entwickelt von Michael Porter im Jahr 2008. Diese Analyse basiert auf der Betrachtung von fünf Wettbewerbskräften, die unterschiedlich ausgeprägt sein können. Dabei wird die Verhandlungsmacht der Abnehmer, Gefährdung durch Ersatzprodukte, Verhandlungsstärke der Lieferanten, Bedrohung durch neue Anbieter und der brancheninterne Wettbewerb analysiert und dargestellt.

Kundenzufriedenheitsbewertung

Im Gesundheitswesen rücken die Kunden und deren Bedürfnisse in das Zentrum der Betrachtung. Wie aus der empirischen Studie der Universität St. Gallen (vgl. Reinecke 2016) hervorgeht, setzen erfolgreiche Unternehmen daher bereits verstärkt auf regelmäßige Kunden- und Mitarbeiterzufriedenheitsmessungen. Die Ergebnisse dienen dazu, Fehler oder Schwachstellen im Prozess zu erkennen und dementsprechend zu handeln, um den Erfolg des Unternehmens sicherzustellen (vgl. Föhrenbach 1995). Darüber hinaus helfen Kundenzufriedenheitsbewertungen, die Wirksamkeit von Marketing- oder Vertriebsaktivitäten besser zuzuordnen.

Um die Kundenzufriedenheit zu ermitteln, haben Medizintechnik-Hersteller verschiedene Möglichkeiten. Auf der einen Seiten kann das Marketing-Controlling auf der Grundlage von Beschwerden, Kundenproblemen oder Mitarbeitereinschätzungen Analysen aufbereiten. Auf der anderen Seite sind Kennzahlen zur Wiederkaufrate der Kunden oder Umsatzentwicklungen einzelner Produkte Indikatoren der Kundenzufriedenheit (vgl. Manser o. J.).

Subjektive, aber aufschlussreiche Methoden stellen direkte Kundenbefragungen dar. Einige der gängigsten Methoden sind:

- Customer-Satisfaction-Score (CSAT) – Zufriedenheitsmessung mittels einer Likert-Skala von 1-5, wobei 5 die höchste Kundenzufriedenheit ausdrückt.
- Customer-Effort-Score (CES) – Kundenbefragung, wie hoch deren Aufwand war bis ein Problem gelöst, die Bestellung platziert oder eine Beschwerde aufgenommen werden konnte. Dabei wird mit einer 5er oder 7er Likert- Skala gearbeitet. Je höher der Wert, desto höher der Aufwand für den Kunden.
- Net-Promoter-Score (NPS) – Die Befragung bezieht sich darauf, ob die Kunden das Unternehmen oder Produkt / Dienstleistung weiterempfehlen würden. Gängig ist hier eine 10er Likert-Skala, wobei Werte zwischen 1-6 als Kritiker und 9-10 als Promoter bewertet werden.
- Persönliches Gespräch – In der Regel wird hier ein persönliches Gespräch von Mitarbeitern des Unternehmens durchgeführt.

In der Medizintechnik gibt es entlang des Versorgungs- und Verkaufsprozesses mehrere wichtige Akteure, wodurch die Feststellung der Kundenzufriedenheit herausfordernder ist als in Branchen, in denen es einen bestimmten Endkunden gibt (z. B. bei Mobiltelefonen).

Auch wenn der Patient im Mittelpunkt der Versorgung und am Ende die Ergebnisqualität (erfolgreiche Therapie) im Vordergrund stehen, ist für die Medizintechnik-Hersteller der Anwender des Produktes der primäre Kunde. Zusätzlich sind weitere Entscheidungsträger innerhalb der privaten und öffentlichen Krankenhausträger (z. B. Einkäufer) mit zu berücksichtigen.

Die vier zuvor aufgezählten Methoden zur Ermittlung der Kundenzufriedenheit können auch in der Medizintechnik angewendet werden. Allerdings beinhalten einige der Methoden gewisse Limitationen. Beim CSAT wird die Zufriedenheit der Ärzte mit den angebotenen Produkten, dem Service oder der Beratung der Außendienstmitarbeiter ermittelt. Eine Limitation der Daten findet sich darin, dass es aufgrund der ordinalen Skalierung keine aussagekräftigen Erkenntnisse zwischen einer Bewertung von vier oder fünf gibt. Darüber hinaus können aufgrund der Abfrage mittels einer Likert-Skala keine neuen Bedürfnisse ermittelt werden.

Die kontinuierliche CES-Befragung misst den Aufwand, der vom Kunden (wie etwa einem Arzt) investiert werden muss, um ein Problem zu lösen oder eine Reklamation aufzugeben. Eine hohe Aufwandsrate, gleichbedeutend mit schlechten Ergebnissen, impliziert beispielsweise mögliche Qualitätsprobleme bei bestimmten Medizinprodukten oder eventuelle Mängel im Kundenservice. Niedrige Aufwandsraten deuten hingegen auf eine hohe Kundenzufriedenheit, da Probleme schnell erkannt und behoben werden. Die gelieferten Erkenntnisse der CES-Methode sind vor diesem Hintergrund für das Marketing-Controlling nützlich, um einzelne Prozesse zu analysieren und Vorschläge zur Optimierung darzulegen. Auftretende Qualitätsprobleme bei Produkten, wie Implantaten, Ultraschall-Geräten oder chirurgischen Instrumenten, müssen rechtzeitig erkannt und bearbeitet werden, um größere Image- sowie wirtschaftliche Schäden zu vermeiden. Nachteil dieser Methode ist, dass nur spezifische Bereiche abgedeckt werden und nicht ein gesamtheitlicher Überblick verschafft wird. Aus diesem Grund ist das CES keine verlässliche Quelle, um ein Gesamtbild der Kundenzufriedenheit zu erhalten.

Die NPS-Methode ist eine der bekanntesten Methoden zur Messung der Kundenzufriedenheit. In der Medizintechnik sind Promotoren und Kritiker wie auch ärztliche Meinungsbildner entscheidend, um Bedürfnisse zu verstehen und zu erkennen. Regelmäßige NPS-Erhebungen entlang des Produktlebenszyklusses geben in jeder Phase Möglichkeiten zu Optimierungen seitens des Marketings. Wenn die NPS-Analyse regelmäßig als Instrument eingesetzt wird, ist auf eine ausreichend große Stichprobe und kurze Zeiträume zwischen Erhebung und Analyse zu achten.

Als weitere Methode zur Messung der Kundenzufriedenheit kann das persönliche Gespräch genutzt werden. Viele Medizintechnik-Unternehmen pflegen sehr enge Kundenbeziehungen mit Anwendern oder deren Einkäufern. Das persönliche Gespräch ermöglicht es, auf unzufriedene Kunden direkt zu reagieren und eine

tiefere Bedarfsanalyse durchzuführen. Die Wahrnehmung der Kundenzufriedenheit ist hier jedoch oft subjektiv und birgt die Gefahr, dass Kunden im direkten Kontakt die negativen Erfahrungen mit dem Produkt, dem jeweiligen Unternehmen oder dessen Mitarbeitern nicht benennen möchten.

Zusammenfassend kann festgehalten werden, dass Marketing-Controller bei Medizintechnik-Unternehmen nicht mit einer Methode zur Kundenzufriedenheitsmessung auskommen. Neben Analysen anhand interner Daten, sollten die Erkenntnisse mit externen Daten abgeglichen werden. Dafür stehen mehrere unterschiedliche Methoden zur Verfügung, um die Limitationen einzelner Methoden auszugleichen und damit ein klares Bild der Kundenzufriedenheit zu erhalten.

Sponsoring-Erfolgsanalysen

Ein von erfolgreichen Unternehmen regelmäßig eingesetztes operatives Marketing-Controlling Instrument ist die Sponsoring-Erfolgsanalyse. Das Sponsoring ist eines von mehreren Kommunikationsinstrumenten des Marketing (vgl. Bruhn 2009, S. 3).

Gemäß einer Kommunikationsstudie aus 2015, in denen 461 Unternehmen in Deutschland mit mehr als 50 Mitarbeitern interviewt wurden (CATI oder Online-Interview), lag der Anteil des Sponsoring- Budgets mit 2,58 Milliarden € bei ca. 9% des gesamten Kommunikationsetats. Darüber hinaus wurde der Etat für die „direkte Wirtschaftskommunikation“ mit knapp 18% angegeben. Diese beinhaltet Messen, Kongresse, Events und Brandparks und steht in einer engen Verbindung zum Sponsoring. Dadurch tragen diese Maßnahmen zur gesamtheitlichen Bedeutung des Sponsorings als Kommunikationsinstrument maßgeblich mit bei (vgl. Zanger 2016, S. 13 f.).

Vor dem Hintergrund der hohen Relevanz von Sponsoring-Aktivitäten ist es wichtig, Effektivität und Effizienz durch das Marketing-Controlling besonders zu überwachen und sicherzustellen. Dabei lässt sich nach Schwizer und Reinecke (2017, S. 25) das Sponsoring in drei Phasen unterteilen:

1. Sponsoring-Engagement (Erwerb der Rechte),
2. Sponsoring-Aktivierung sowie
3. Implementierung und Optimierung.

Jede der drei Phasen ist vom Controlling zu begleiten. Vor der Entscheidung für eine bestimmte Art des Sponsoring-Engagements sind die unterschiedlichen Möglichkeiten mit den Unternehmenszielen abzugleichen. Die Passgenauigkeit des Sponsorings beeinflusst zum Beispiel Ziele, wie Image oder Bekanntheitsgrad. Die im Vorfeld getroffenen Überlegungen helfen im Anschluss, die Effektivität und Effizienz der Aktivitäten besser zu analysieren. Nach Abschluss des Sponsoring-Vertrages startet die Aktivierungsphase. In dieser Phase werden alle Maßnahmen getroffen, um die definierte Botschaft des Sponsorings an die Zielgruppe heranzutragen. Idealerweise impliziert dies, dass die Botschaft vor und nach der Zeit des Sponsorings verbreitet wird. Aufgaben des Sponsoring-Controllings beinhalten vor Beginn in der Aktivierungsphase die Budgetierung und Ressourcenplanung (personeller und finanzieller Aufwand). Die

Implementierung und kontinuierliche Verbesserung der Aktivierungsmaßnahmen verlangen nach vielen Ressourcen, bieten aber durch klare Aktivierungsziele mit Key-Performance-Indikatoren (KPI) die Chance, sich vom Wettbewerb abzuheben. Sofern es als Kommunikationsinstrument des Marketings strategisch eingesetzt werden soll, ist die Erfolgsmessung für eine Vielzahl an eingesetzten Kommunikations-Maßnahmen zu planen (vgl. Bruhn 2009, S. 3).

In der dritten und letzten Phase *Implementierung und Optimierung* geht es vorrangig um den Nachweis der Wirksamkeit der Sponsoring-Maßnahmen. In diesem Zeitraum erfolgt die Erfolgsmessung anhand der vorher definierten KPI`s. Sofern die Maßnahmen über einen längeren Zeitraum erfolgen, können über permanente oder wiederkehrende Messungen bereits Maßnahmenoptimierungen vorgenommen werden. Bei der Messung des Einflusses von Sponsoring-Maßnahmen auf die Produktabsätze ist zu beachten, dass mehrere Einflussfaktoren auf die Kaufentscheidung einwirken. Das Sponsoring-Controlling sollte sich von daher auf *die* KPI's fokussieren, die sich durch Sponsoring-Engagement direkt beeinflussen lassen (z. B. Reichweite).

In der Medizintechnik wird das Sponsoring als ein Instrument der Marketing-Kommunikation eingesetzt. Sponsorings können hierbei auf verschiedenen Ebenen stattfinden. Laut einer empirischen Studie aus 2019, an der 233 Marketing-Manager amerikanischer Gesundheits-Unternehmen teilnahmen, lag das durchschnittliche Marketing-Budget bei $10,49 Mio. Dabei stammten 80% der Befragten aus Unternehmen, die einen Umsatz von $500 Mio. oder mehr pro Jahr erzielen. Das lässt auf ein Marketing-Budget von ca. 2% vom Gesamtumsatz schließen. Heruntergebrochen auf Medizintechnik-Unternehmen lag jedoch das zur Verfügung gestellte Budget mit $7,8 Mio. im Verhältnis zu Pharma- ($11,56 Mio.) oder Biotech-Herstellern ($9,05 Mio.) deutlich niedriger (vgl. Daniels, 2016).

Auffällig ist in der Betrachtung der Budgetaufteilung, dass Medizintechnik-Unternehmen mit Abstand das meiste Marketingbudget für „Professional Meetings / Conferences“ und „Sales Representatives“ ausgeben. Die Ausgaben liegen mit 14,7% für „Professional Meetings / Conferences“ fast 3-mal so hoch wie in den Bereichen von Pharma (6,3 %), Biotech (4,9%) und Diagnostics (5,7%) (vgl. Daniels 2016).

Der amerikanische Gesundheitsmarkt unterliegt anderen Rahmenbedingungen und ist anders ausgestaltet als der in Deutschland. Dennoch können die Ausgaben im Bereich „Professional Meetings / Conferences“ eine Tendenz für den deutschen Markt und speziell für Sponsoringaktivitäten im Bereich Bildung (Fortbildungs-Veranstaltungen und Kongresse) bieten, da diese beiden Marketing-Maßnahmen in der Medizintechnik eng verbunden sind.

Einen weiteren Aufschluss über die ausgewählten Sponsoring-Engagements deutscher Gesundheits-Unternehmen liefert die in 2018 veröffentlichte Studie (Desktop Research) von Research Tools (2018). In dieser Studie wurden 692 Sponsoring-Projekte von zehn deutschen Pharmaherstellern, wie Astra Zeneca, Boehringer Ingelheim, Merck oder Bayer Healthcare, analysiert. Der Analyse zufolge werden die Sponsoring-Etats hauptsächlich für soziale Projekte (49%), dicht gefolgt von Bildung und mit großem Abstand für Sport-

Sponsorings eingesetzt. Sponsoring-Möglichkeiten in den Bereichen Kultur und Umwelt wurden nur sehr selten genutzt. In Bezug auf die gesponserten Projekte bei Sozialem und Bildung stehen gesundheitsbezogene Stiftungen und Vereine sowie medizinische Symposien und Kongresse mit ca. 70% der gesamten Aktivitäten bei den Pharma-Herstellern deutlich im Fokus. Darüber hinaus konnte ein langfristiges Engagement der Unternehmen, entweder mehrmals jährlich oder permanent (33% der Projekte), für die Sponsoring-Engagements ausgemacht werden (vgl. Research Tools, 2018).

Zu detaillierten Sponsoring-Engagements von deutschen Medizintechnik-Herstellern gibt es bisher wenig veröffentlichte Literatur. Der Vergleich der o.a. amerikanischen Studie von MM&M/Deloitte (vgl. Daniels 2019) im Vergleich zu den Ergebnissen der Studie von Research Tools des Sponsoring-Engagements deutscher Gesundheitsunternehmen legt die Vermutung nahe, dass deutsche Medizintechnik-Unternehmen einen ähnlich hohen Anteil für Sponsorings budgetieren.

Fraglich ist, welche entscheidenden Aufgaben hierbei dem Marketing-Controlling von Medizintechnik-Unternehmen zukommen. Auf Basis der gewonnenen Erkenntnis, dass der Sponsoring-Erwerb sich häufig auf Stiftungen, Vereine, Symposien und Kongresse konzentriert, wird nachfolgend ein fiktives Beispiel aus der Medizintechnik zur praktischen Umsetzung des Sponsoring-Controllings, beschrieben. Es wird in diesem Beispiel und der grundsätzlichen Analyse nur auf den Inhalt des Kommunikationsinstrumentes des Sponsorings eingegangen und nicht auf dessen rechtliche, regulatorische und ethische Rahmenbedingungen.

Beispiel:

Das Unternehmen Heile-Gut GmbH ist seit 12 Jahren im Gesundheitswesen als Wundversorgungshersteller tätig und beschäftigt 40 Mitarbeiter. Die Unternehmensführung steht am Anfang der Produkteinführung einer innovativen Wundauflage. Einer wissenschaftlichen Studie zufolge bietet das Produkt den potenziellen Zielgruppen, Wundmanagern und Chirurgen, wesentliche Mehrwerte. Über eine längere Verweildauer der Wundauflage am Patienten (höheres Aufnahmevolumen) sowie ein verbessertes Handling (klebt seltener am Handschuh des Anwenders und reduziert den Materialverbrauch) ist eine höhere Wirtschaftlichkeit gegenüber den konkurrierenden Herstellern darstellbar. Der Wundversorgungshersteller hat sich folgende Ziele gesetzt:

- Steigerung des Bekanntheits- und Nutzwertes der neuen Wundauflage um 25% und
- Steigerung des Produkt-Absatz um 30%.

Es existieren für den Hersteller eine breite Auswahl an Sponsoring-Möglichkeiten. Dafür wurden im Vorfeld verschiedene Kongresse und Symposien anhand eines Scoring-Modells bewertet. Kriterien waren unter anderem: Teilnehmeranzahl und Berufsgruppe, Art des Fachbereiches, Reichweite, wissenschaftlicher Inhalt und Sponsoring-Paketangebote, die mit den eigenen Unternehmenszielen abgeglichen wurden. Auf Grundlage dieser Analyse fiel die Wahl auf die Teilnahme an den Wundkongressen IWC und DeWU. Nach Erwerb des Sponsoring-Engagements erstellte das Marketing die in Abbildung 3 benannten Aktivierungsmaßnahmen, um

das Sponsoring und die damit verbundenen Botschaften für die Zielgruppe (Wundmanager) sichtbar zu machen. Zu den Maßnahmen gehören u.a. das Erstellen eines Kongresskonzeptes, die Veröffentlichung eines Artikels in einer Fachzeitschrift bevor der Kongress stattfindet wie auch die Bekanntgabe des Sponsorings über Social-Media-Kanäle. Entlang der Aktivierungsphase hat das Sponsoring-Controlling die Budgetüberwachung durchgeführt und stetig die einzelnen Maßnahmen auf Effektivität und Effizienz überprüft, um zwischenzeitlich schon Verbesserungen zu erzielen.

In der Implementierungs- und Optimierungsphase steht die Erfolgskontrolle im Vordergrund. Dabei sind vordefinierte KPI`s für die Analyse hilfreich. Das Unternehmen hat sich für die Besucherzahlen als quantitativen KPI und Besucherbefragungen als qualitativen KPI entschieden. Die Messungen der Besucherzahlen am Stand und bei den Vorträgen liefern Erkenntnisse zur Wahrnehmungswirkung. Sie werden vom Unternehmen ins Verhältnis zu denen der Mittbewerber und zur Gesamtbesucherzahl der Kongresse gesetzt. Standbefragungen dienen als qualitatives Instrument, ob und wie die gewünschte Botschaft beim Zielpublikum ankommt. Im Endeffekt konnte das Wundversorgungsunternehmen in Bezug auf die Effektivität feststellen, dass der Bekanntheitsgrad um 37% und die Umsätze um 12% gestiegen sind. In Bezug auf die Effizienz war der Ressourcenverbrauch für Headcounts und Budget immens. 65% der Ressourcen aus dem Marketing wurden für die Sponsoring-Aktivitäten eingesetzt. Durch diese Maßnahmen mussten anderweitig unterstützende Maßnahmen des direkten Vertriebs deutlich reduziert werden.

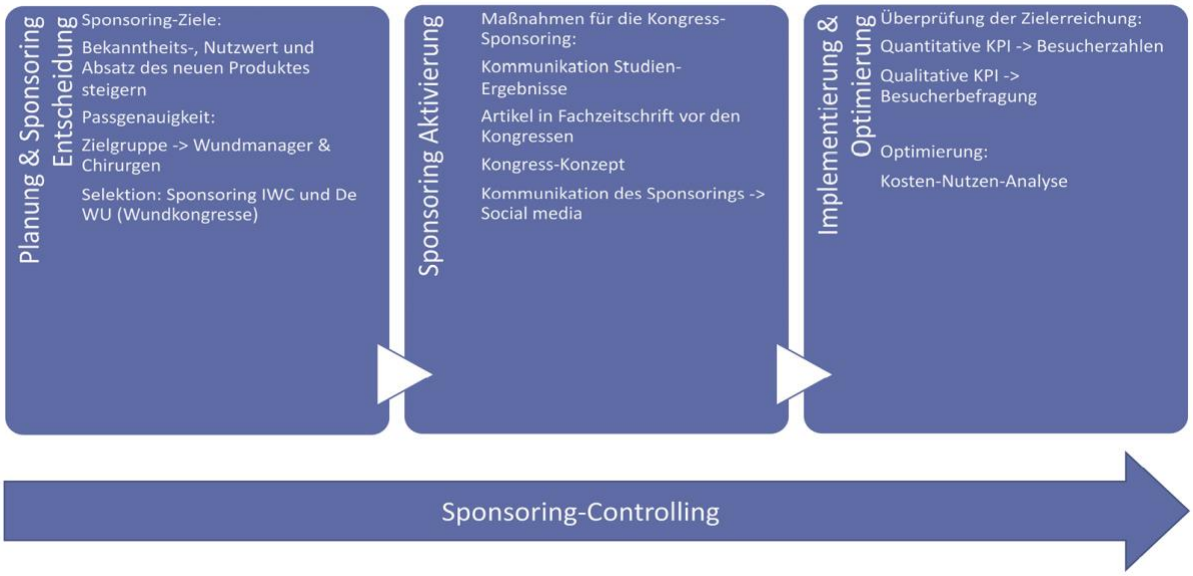

Abb. 3: Beispiel Sponsoring-Controlling (Quelle: Eigene Darstellung in Anlehnung an Schwizer, 2017, S. 28)

Der Unternehmensleitung ist bewusst, dass Kaufentscheidungen von vielen Faktoren beeinflusst werden, die schwierig nachweisbar sind. Zur Erreichung der Ziele werden vom Marketing-Controlling, neben dem

Umsatzzuwachs, auch nicht direkt umsatzrelevante Ziele, wie die Erhöhung des Bekanntheitsgrads und die Wahrnehmung des Kunden, ausgegeben.

Zusammenfassend kann festgehalten werden, dass aufgrund des hohen Stellenwertes von Sponsoring als Kommunikations-Instrument innerhalb des Marketings von Healthcare-Unternehmen Ressourcen für das begleitende Controlling zwingend notwendig sind. Durch eine professionelle Planung, Analyse, Umsetzung und Kontrolle der Aktivitäten ist eine Erfolgsbewertung der Effektivität und Effizienz von Sponsoring möglich (wenn auch nicht zu 100%); dies stellt die Optimierung zukünftiger Sponsoring-Engagements sicher. Dafür sind die relevanten Ziele im Vorfeld zu definieren und anhand von darauf abgestimmten Key-Performance-Indikatoren prozessbegleitend und im Nachhinein zu vergleichen.

Herausforderungen bestehen hier für Unternehmen, Daten, wie etwa Kundengespräche während/nach Kongressen, zu sammeln oder Verbindungen zwischen den unterschiedlichen Maßnahmen, wie App/Website-Besuchen, Teilnahme an den wissenschaftlichen Vorträgen und Kundenbesuche seitens des Außendienstes, herzustellen. Diese Herausforderungen erschweren es dem Sponsoren, die Wirkung im Verhältnis zu den bereitgestellten Ressourcen sowie die vorher definierte Zielerreichung zu messen. Am Markt existieren diverse Softwaretools in Form von Customer-Relationship-Management Systemen, wie Salesforce, LinkedIn oder Analytics 360 (Google), die derartigen Analysen unterstützen.

2.3. Digitalisierung und Big Data als Möglichkeiten eines erweiterten Marketing-Controllings

Wie eingangs beschrieben, ist die Digitalisierung ein Schlüssel zu einer verbesserten Versorgung im Gesundheitswesen. Mit der Einführung der Gesundheitskarte in 2003 und der elektronischen Patientenakte in 2008 sollte die Digitalisierung positiv vorangetrieben werden. Das Ziel der Digitalisierung ist dabei der erleichterte oder teilweise automatisierte Informationsaustausch, um die verschiedenen Sektoren in der Versorgung zu verbinden. Laut einer weltweiten Bertelsmann-Studie (2018) lag Deutschland im Digital-Health-Index auf Platz 16 von 17. In den Ländern auf den ersten Plätzen, wie Estland, Kanada und Dänemark, werden die elektronische Patientenakte oder elektronische Rezepte bereits umgesetzt.

Erste Ansätze der Digitalisierung wurden auch in der deutschen Patientenversorgung eingeführt, jedoch erwies sich die skeptische Haltung der beteiligten Akteure als entscheidende Hürde. Durch die Digitalisierung waren neue Prozesse gefordert und Institutionen sollten verbunden werden, doch noch immer kommunizieren 94% der Krankenhäuser und Arztpraxen vorrangig in Papierform (vgl. Ex und Amelung, 2019, S. 111 f.). Diese Zahlen stehen im Einklang mit der Analyse von 2015 (vgl. Digital intelligence institute 2015, S. 11), in der mehr als 2/3 aller Einrichtungen die medizinischen Prozesse mit 50% oder mehr in Papierform beschreitet. Auch wenn der Bedarf zu einem digitalen Wandel hoch ist, spiegeln sich die unterdurchschnittlichen Ergebnisse im Wirtschaftsindex in den Digitalisierungsstrategien der Unternehmen wieder. Mehr als die Hälfte der Medizintechnik-Unternehmen besitzen keine klar definierte

Digitalisierungsstrategie und investieren, im Verhältnis zu den Gesamtausgaben, relativ geringfügige Beträge in digitale Projekte (vgl. Dispan 2020, S. 55).

Obwohl der aktuelle Stand ein eher negatives Bild der Digitalisierung zeichnet, so bietet diese doch große Chancen für das Gesundheitswesen. Ob in der Gesundheitsversorgung, Forschung oder Prävention und Diagnose von Krankheiten, in jedem dieser Bereiche können durch die Vielzahl an generierten Daten Optimierungen erreicht werden. Auf der anderen Seite darf nicht vergessen werden, dass beim Umgang mit sensiblen patientenbezogenen Gesundheitsdaten ein hoher Anspruch an Datenschutz und IT-Sicherheit an die beteiligten Akteursgruppen gestellt wird (vgl. Blachetta 2016, S. 25).

Mit dem steigenden Datenvolumen von strukturierten und unstrukturierten Daten im Gesundheitswesen (vgl. W. Raghupathi & V. Raghupathi 2014) und dem Bedarf an schnellen und aussagekräftigen Auswertungen bekommen Big Data und Business Analytics (zumeist auf Big Data aufbauend) eine wachsende Bedeutung zugeschrieben. Über Big Data Analytics ist ein geschäftlicher Mehrwert erreichbar. Dieser Mehrwert für Unternehmen im Gesundheitswesen lässt sich in fünf Kategorien unterteilen: IT-Infrastruktur Vorteile, Operativer Nutzen, Organisatorischer Nutzen, Management Vorteile sowie strategische Vorteile. Durch die niedrige Adoption von Informations-Technologie (IT) im Gesundheitswesen gibt es derzeit allerdings nur wenige primäre Datensätze, um wichtige Aspekte wie die organisatorische Performance zu analysieren und zu bewerten (vgl. Wang et al. 2018). Im Gegensatz zu „eHealth“-Anwendungen, die die Vernetzung und Kommunikation zwischen Organisationen, Sensoren, Menschen und IT-Systemen im Gesundheitswesen umsetzen, sind Business Analytics Anwendungen auf Basis von Big Data in der Lage, Analysen, Auswertungen und Aggregationen von Daten in entscheidungsrelevante Informationen umzuwandeln (vgl. Blachetta 2016, S. 53).

Letztendlich bietet das Gesundheitswesen Big Data eine Vielzahl an Datenquellen. Zusammengefasst können sie in sieben Quellen geclustert werden:

1. Medizinische Daten,
2. öffentliche Gesundheitsdaten,
3. Versicherungsdaten,
4. Forschungsdaten,
5. individuelle, durch Nutzer generierte Daten,
6. Pharma- / Medizintechnik-Daten sowie
7. nichtklassische Gesundheitsdaten.

Um die Daten aus verschiedenen Datenquellen mittels Business Analytics zu analysieren und entscheidungsrelevante Informationen zu generieren, können verschiedene Technologien und Speichersysteme eingesetzt werden. Letztendlich möchten die Anwender Erkenntnisse zu vier Zielen erhalten, dem Reporting, dem Monitoring, der Evaluation und der Prognose.

Neben den Anwendungsfeldern, wie Gesundheitsprävention und Leistungs- und Qualitätsbeurteilung, liefert Business Analytics auch zu Prozessverbesserungen wichtige Erkenntnisse. Dabei können organisationsbezogene Daten, wie interne Abrechnungsdaten oder Daten aus sozialen Netzwerken des Unternehmens, analysiert und als Informationen für die relevanten Entscheidungsträger aufbereitet werden, um Bereiche für Optimierungsmöglichkeiten aufzuzeigen (vgl. Blachetta 2016, S. 58 f.).

Unternehmen, die bei internen Prozessen bereits mit großen Datenmengen arbeiten, können während des Forschungsprozesses oder der Markteinführung über beispielsweise Real World Data Analysen zur Wirksamkeit von Medikamenten erstellen. Diese Analysen können als Risiko-Nutzen-Profile genutzt werden, um Markteinführungskosten zu reduzieren und Preisverhandlungen mit zu beeinflussen (vgl. Blachetta 2016, S. 65). Von Unternehmen, die im Bundesverband der Medizintechnologie sind, haben in einer Umfrage von 2019 82% angegeben, bereits digitale Lösungen für die Prozess- und Produktverbesserungen zu nutzen. Allerdings setzen nur 13% der Unternehmen bereits Big-Data-Anwendungen ein (vgl. BVMed 2020, S. 13).

In Verbindung mit Marketing-Controlling Instrumenten, wie etwa Kundenzufriedenheitsmessungen oder Sponsoring-Erfolgsanalysen, können die Digitalisierung und insbesondere Big-Data-Anwendungen viele Herausforderungen lösen. Aktuell beherrschen persönliche Interaktionskanäle die Kundenbeziehung. Das ist insbesondere ersichtlich, wenn es komplexe Sachverhalte, wie die Befriedigung individueller Kundenbedürfnisse durch die Mehrwerte eines bestimmten Medizintechnikproduktes, betrifft. Entlang des Kundenverkaufszyklus werden sowohl bei Kundenzufriedenheitsmessungen oder Erfolgskontrollen in Form von Wahrnehmungs- und Einstellungswirkungen verschiedenste Kanäle genutzt. Einige Kanäle davon sind Online- und Offline- Umfragen, Telefoninterviews wie auch direkte oder indirekte (über Drittparteien) persönliche Gespräche. Durch die hohe Anzahl verschiedener Interaktionskanäle, die alle im Wettbewerb zueinanderstehen, existieren erhebliche Konfliktpotentiale. Diese Konflikte resultieren in stückhaften Informationszuordnungen und -verbindungen (vgl. Avramakis 2020, S. 228 f.).

Auch wenn komplexe Produkte oder Dienstleistungen weiterhin soziale Interaktionen benötigen, können durch den Einsatz von digitalen Plattformen (z.B. LinkedIn), sozialen Netzwerken wie Facebook und CRM-Tools wie Salesforce, Daten über Verhaltensweisen, Reaktionen oder Wünsche der Kunden gesammelt werden. Durch Big-Data-Anwendungen werden Daten aus sozialen Netzwerken, Video-Portale in verschiedenen Sprachen, Salesforce-Eintragungen in relativ kurzer Zeit ausgelesen und analysiert. Die Erkenntnisse helfen dem betreffenden Unternehmen, auf Kundenbedürfnisse kurzfristig zu reagieren, innovative Produkte zu entwickeln und Sponsoring-Engagements zu optimieren. Darüber hinaus überwinden Big-Data-Anwendungen zeitliche Herausforderungen wie bei der Net-Promoter-Score Methode (Zeit zwischen Erhebung und Analyse) und haben einen starken Einfluss auf optimierte Kundenzufriedenheitsmessungen.

Auf weitere Anwendungs- und Optimierungsmöglichkeiten, wie Produkt- oder Prozessoptimierungen durch Machine to Machine (M2M) Learning oder eine erweiterte Informationsversorgung durch Artificial

Intelligence (AI) Anwendungen, wird aufgrund der Komplexität dieser Themenfelder hier nicht weiter eingegangen.

3. Schlussbetrachtung

Deutsche Medizintechnik-Unternehmen befinden sich seit 2010 in einer der stärksten wachsenden Branchen. Trotz überdurchschnittlicher EBIT-Margen im Verhältnis zu anderen Industrien, stehen die Unternehmen aufgrund kontinuierlicher Veränderungen jedoch vor großen Herausforderungen. Neue rechtliche und regulatorische Rahmenbedingungen sorgen für erhöhte und mit Kosten verbundene Anforderungen an die Hersteller und ihre Medizinprodukte. In Verbindung mit den wirtschaftlichen Herausforderungen der Leistungserbringer, etwa den Krankenhäusern, müssen sich Medizintechnik-Unternehmen neue Lösungswege überlegen. Alte Marketing-Konzepte sind mit neuen Konzepten wie SAVE zu überdenken und zu überprüfen. Durch einen kundenorientierten Fokus, zugeschnitten auf das Erkennen und Befriedigen der Kundenbedürfnisse und das klare Herausstellen der unternehmenseigenen Mehrwerte, lassen sich auch in einem starken Wettbewerb Vorteile erzielen.

Um weiterhin konkurrenzfähig zu bleiben, bedarf es einer kontinuierlichen Sicherstellung der Wirksamkeit und Wirtschaftlichkeit von Markt- und kundenorientierten Marketing-Aktivitäten. Aus diesem Grund ist es für Medizintechnik-Unternehmen zukünftig entscheidend, über das Marketing-Controlling Planungen, Analysen und Umsetzungen zu begleiten.

Zwei Instrumente, die als Eckpfeiler eines Marketing-Controllings von Medizintechnik-Unternehmen eingesetzt werden können, sind die der Kundenzufriedenheitsbewertung und der Sponsoring-Erfolgsanalyse. Als strategisches Controlling-Instrument liefern viele aktuelle Bewertungs-Methoden alleinstehend nicht ausreichend Aufschluss über die Kundenzufriedenheit. Um entscheidungsrelevante Informationen in kürzester Zeit zu erhalten, sind Investitionen in digitale Plattformen und soziale Netzwerke sowie der Einsatz von Big-Data-Anwendungen unabdingbar. Dadurch können diverse Datenquellen, wie Umfragen, soziale Netzwerke oder CRM-Systeme, gemeinsam genutzt werden und dem Marketing-Controlling Analysen zur Kundenzufriedenheit und nachfolgend entscheidungsrelevante Informationen zu Optimierungsmöglichkeiten der Prozesse oder der Medizinprodukte ermöglichen. Ähnlich gestaltet es sich bei der Sponsoring-Erfolgsanalyse. Während ein signifikanter Teil des Gesamtbudgets für Sponsoring-Engagement in der Medizintechnik aufgewendet wird, ist es in Anbetracht der zu erwartenden finanziellen Herausforderungen in den nächsten Jahren elementar, den Prozess über ein Sponsoring-Controlling in jeder Phase zu begleiten. Die Messbarkeit von ökonomischen Zielen und Erfolgsfaktoren, wie Image-Gewinn oder Wahrnehmungs- bzw. Einstellungswirkungen, wird durch den Einsatz von digitalen CRM-Systemen und Anwendung von Big Data Analytics auf ein neues Niveau gehoben. Durch den Einsatz der Tools lassen sich zudem, aus Sicht des Marketing-Controllings, Ressourcen für Prozessverbesserungen bereitstellen und rechtfertigen.

Insgesamt lässt sich aufgrund der beschriebenen Erkenntnisse konstatieren, dass Medizintechnik-Unternehmen ohne Investitionen in digitale Technologien in der Zukunft nicht mehr wettbewerbsfähig sein werden. Gerade im Hinblick auf ein effizientes Marketing-Controlling eröffnet sich digitalisierten Unternehmen die Möglichkeit, durch aufbereitete Analysen aus verschiedenen Datenquellen in kurzer Zeit Prozessoptimierungen vorzunehmen und Kundenbedürfnisse frühzeitig zu identifizieren.

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5.2 Article 2: The economic impact of standardization and digitalization in the operating room: a systematic literature review

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Abstract

Background: Hospital face increased resource constraints and competition. This escalates the need for efficiency optimization especially in resource-intense areas, such as the Operating Room (OR). Efficiency cannot happen at expenses of patient outcomes. Innovative digital support systems (DSS) have been introduced into the market to support established standardization methods of intraoperative workflows further.

Objective: This review aimed to analyze whether applied standardization methods and implemented DSS of intraoperative surgical workflows lead to increasing efficiency and demonstrate economic improvements.

Methods: A systematic review of intraoperative surgical workflows standardization and digitalization was performed. Journal articles and reviews from 2000 to 2023 were retrieved from EBSCO, PubMed, and Scopus databases, as well as the internal database of Johnson & Johnson.

Results: 17 articles showed a significant increase in efficiency through standardization, which led to cost reductions between $70.20 to $3,516 per case without negatively impacting quality. Five additional articles on DSS demonstrated a significant positive impact on efficiency and quality. Reduction in OR-time between 6% to 22% per case was one main contributor. No literature on DSS revealed any correlated economic impact.

Conclusions: Selected standardization methods and introduced DSS for intraoperative surgical workflows effectively increase efficiency while maintaining or even improving quality. Demonstrated cost-effectiveness of non-digital standardization methods across surgical areas requires more research on complex and resource-intensive procedures and the economic value of DSS to support hospital management's strategic decisions to overcome the increasing economic burden.

Keywords*:* standardization, digital support system, surgical process, operating room, intraoperative, cost efficiency

Introduction

European hospitals are confronted with increasing economic pressure. Intense competition among private and public hospitals and a dual financing system, which provides insufficient financial support for investments, create a strong need to control the costs per patient [1]. To overcome this economic burden, hospitals continuously seek to optimize the efficiency of patient pathway processes. Efficiency is measured by assessing process time, quality, capacity, profitability, productivity, and liquidity [2]. Since the operating room (OR) accounts for approx. 40% of the total operational costs of a hospital [3], optimization of surgical workflow efficiency has become one of the main target areas [4], [5]. Research on efficiency management demonstrated that rationalizing and standardizing surgical processes can significantly enhance efficiency [6], [7]. The increase in OR efficiency due to reduction of preparation time, procedural time, or turnover time can result in an increase of capacity and better utilization of staff [8], [9]. Hospitals have adopted well-known and successful methods from other industries, such as Six-sigma or lean management, to standardize surgical processes. [5], [10] Clinical research demonstrated that such methods applied to preoperative processes or checklists significantly improve the start of procedures on-time and decrease the turnover time of patients. As a result, higher capacity led to increased procedures and less overtime, which significantly reducing costs [5], [10]. In addition, lower complication rates during or after surgical procedures shorten length of stay and demonstrate the interdependence between efficiency and quality at a hospital [8], [11].

Innovative management information systems (MIS) have been developed to optimize efficiency and resource utilization [12]. The development of generic surgical process models (gSPM) paved the way to increased evidence usage for clinical and administrative decision-making. It allowed us to compare surgical strategies, optimize perioperative clinical pathways (efficiency and quality), and develop surgical workflow management systems [13].

Firstly, this literature review analyzes how existing literature studies the efficiency and economic outcome of standardization of intraoperative surgical workflows. Secondly, the review analyzes the implementation and correlated impact on efficiency, quality, and economics of digital support systems (DSS) on intraoperative surgical workflows. This review defines DSS as IT solutions which function as surgical workflow management systems and provide data elements, such as checklists, preference cards or each procedure step to the entire surgical team.

Related Work and Research Framework

Developing and implementing standardized processes of surgical procedures have a significant impact on efficiency and quality. Clinical research has shown that intraoperative workflow standardization leads to reduced operative time. Changing the existing standard procedure and re-engineering the surgical process

decreased the operative time of carpal tunnel decompression cases by 20% [14]. Research also demonstrated that implementing high-resolution standardized protocols reduced the number of micro-complications (MC) in general surgery procedures. Instruments' change and communication-related interruptions primarily drove the occurrence of MCs. Introducing a high-resolution standardized protocol reduced the delay in surgery from 15.6 min/h to 10.6 min/h. This fact correlated with an 8% decrease in operating time per patient, resulting in cost savings of 149€ per case [15]. Alvarez et al. demonstrated in their literature review that standardized ERAS (Enhanced Recovery After Surgery) protocols in bariatric surgery led to benefits such as reduced OR time, rapid patient turnover and decreased healthcare costs [16].

The introduction of IT solutions has shown that digital decision support systems increase efficiency in emergency and trauma departments. Lee et al. revealed that workflow optimization, supported by a digital decision support system, resulted in a 16% higher throughput of patients in the Emergency department [17]. Referring DSS to intraoperative surgical workflows, Feige et al. demonstrated in clinical research that Management-Information-Systems (MIS) are suitable for standardizing surgical workflows and increasing the efficiency of functional endoscopic sinus surgeries (FESS) [7]. A MIS, called "Surgical Procedure Manager" (SPM), was implemented in the OR at a private hospital in Germany to conduct the research. The SPM functions based on predetermined surgical operation handbooks, describing the work and each procedure step. By digitally displaying and voice-assisting surgical steps, regular and exceptional workflows, critical anatomical structures, medical devices and their handling, the SPM virtually guides the OR-Team through each procedure [7], [8]. Implementing the SPM resulted in higher efficiency by saving 14,3% of OR-time (skin to skin time), reducing the use of surgical instruments by 45,9% and change of instruments during the procedure by 41,7% [7].

To further investigate the economic impact of standardized and digitalized intraoperative processes, the research framework for literature reviews of Moher et al. was applied [18].

Methodology

A systematic literature review (SLR) is a process to evaluate and interpret all available and relevant literature to answer specific defined research questions or a topic area. *"Systematic reviews aim to present a fair evaluation of a research topic using a trustworthy, rigorous, and auditable methodology" [19]*. For this SLR, we followed the process of Kitchenham and Charters, which divides the process into three phases: planning, conducting and reporting the review [19].

The research questions behind the SLR were the following:

1. Which methods (interventions) of standardization have been applied to intraoperative surgical workflows to measure efficiency and the economic impact?
2. What is the economic impact of standardization methods for intraoperative surgical processes?

3. What are the main parameters for the measurement of efficiency and economical outcomes?
4. Which DSS for intraoperative surgical process management has been used that also demonstrates an impact on efficiency, quality, and economics?
5. What is the impact of DSS of intraoperative surgical processes on efficiency and quality?
6. What is the impact of DSS on intraoperative surgical processes economically?

Planning the review

A qualitative research checklist for SLRs has been chosen to determine qualitative relevant publications. The most used tool in health-related areas for quality assessments is the Critical Appraisal Skills Program (CASP 2018), approved by the Cochrane Qualitative and Implementation Methods Group [20]. The CASP checklist from 2018 for SLRs is to ensure that identified literature meets the main research questions, comprises an adequate research methodology, includes data aggregation that matches the research questions and contributes a significant value to the scientific society.

To meet the above-mentioned quality requirements, the focus of this SLR has been set on primary and secondary studies published in academic and peer-reviewed journals. Books have been excluded from this search. Articles, reviews, and abstracts were retrieved from EBSCO, PubMed, Scopus and internal databases of Johnson & Johnson. Since the standardization of surgical workflows, supported by digital technology, has been the focus of medical research for about twenty years, the search timeline was defined as between 2000 and 2023 [8], [13].

Conducting the review

Following the strategy of the planning process for the SLR, search criteria were defined as shown in table 1. Those search terms were divided into general search terms and several keywords. “Operating room”, “digital workflow”, and “costs” were determined to be the general search terms. In various combinations, references were considered on the information of the following keywords: “healthcare”, “hospital”, “cost efficiency”, “surgery”, “surgical process”, “intraoperative”, “lean management”, “digital-support tool”, “IT-system”, “management-information-software”. Apart from the data source of Johnson & Johnson, which included studies in English and German, literature in English only was considered. Defining and applying search terms in several combinations and pre-determine quality conditions for this SLR can lead to the exclusion of relevant literature [21]. On the other hand, a systematic approach guarantees replicability and quantification of research [22], [23].

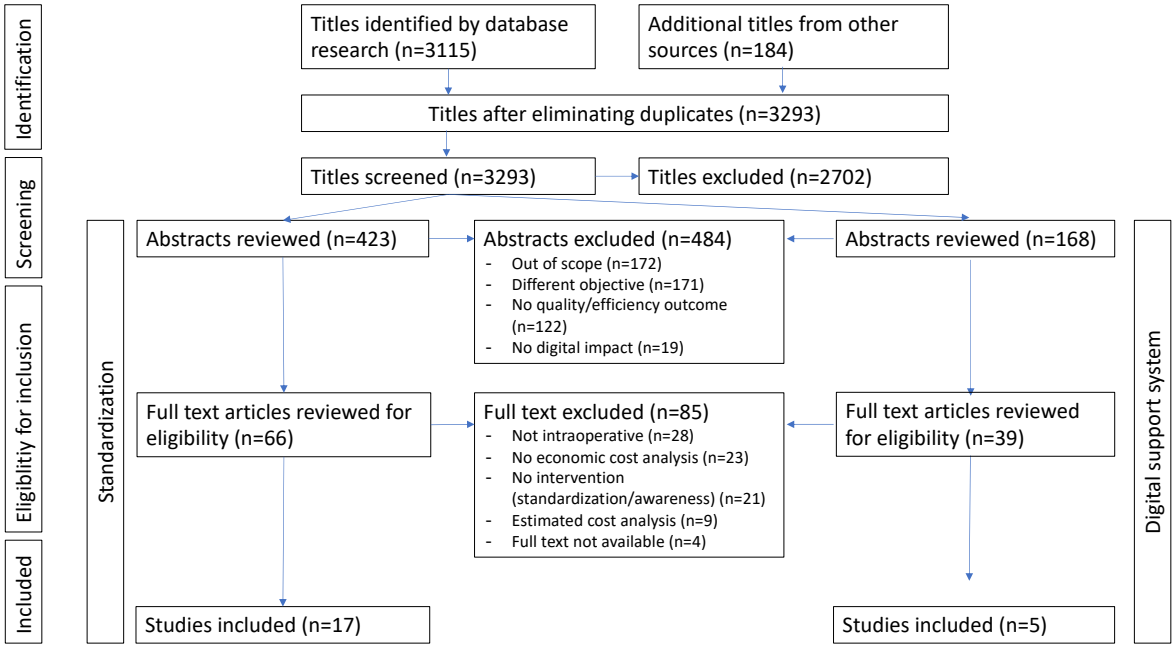
Table 1: Illustrates the search criteria of the SLR and categorized by selected data sources.

Search Criteria						
Data source	Date of search	Date of publications	Study selection criteria	General terms	Search terms	Language
Ebsco	01.12.20-01.03.2021	2000-2021	Peer reviewed, journal articles	Operating room, digital workflow, Cost	Healthcare, hospital, surgical process, surgery, intraoperative, standardization, lean management, cost efficiency, digital, digital support tool, Management-Information-system, IT-System	English
Pubmed	01.12.20-01.03.2021	2000-2021	Journal Articles, Meta-Analysis, RCT, Review, Systematic review, Clinical trial	Operating room, digital workflow, Cost	Healthcare, hospital, surgical process, surgery, intraoperative, standardization, lean management, cost efficiency, digital, digital support tool, Management-Information-system, IT-System	English
Scopus	01.12.20-01.03.2021	2000-2021	Article, journal, review	Operating room, digital workflow, Cost	Healthcare, surgical process, surgery, intraoperative, Standardization, lean management, cost efficiency, digital, digital support tool, Management information system, IT-system	English
Scopus	08.03.23-16.03.2023	2000-2023	Article, journal, review, abstract, conference paper	Operating room, digital workflow, Cost	Healthcare, surgical process, surgery, intraoperative, Standardization, lean management, cost efficiency, digital, digital support tool, Management information system, IT-system	English
Internal J&J data sources	01.12.20	2000-2018	Journal articles, peer reviewed			English, German

Reporting the review

The systematic literature search was conducted between October 2020 and March 2021 and broadened for digitalization in March 2023. Titles, abstracts and full texts were examined against inclusion and exclusion criteria. The flow of information during the different phases is shown in figure 1.

Fig. 1. Flow of information based on Moher [18] The systematic literature search has been divided into articles on “Standardization“ and “Digitalization“, resulting in 22 relevant articles.



The search resulted in 3115 journal articles and literature reviews from EBSCO, PubMed and Scopus databases. 184 additional articles were retrieved from the database of Johnson & Johnson. The abstract review included 423 relevant studies of hospitals´ methods (interventions) for standardization or the creation of cost awareness. An additional 168 abstracts for the “digital support system” category were reviewed, including literature concerning digital solutions or software being implemented in a hospital or operating room (OR). In total, 484 studies were excluded, mainly because they did not match the topic (n=172), different objectives (n=171) or lacked precise analysis of efficiency and quality outcome. Within the “eligibility for inclusion” phase, 105 full-text articles were reviewed, 66 appeared to be relevant for the category of standardization and 39 for “Digital support system”. Finally, 17 studies met the inclusion criteria of standardization and cost awareness. However, no relevant literature on “digital support system”, including economic cost analysis, was found, so these exclusion criteria were not applied for this literature review stream. It resulted in 5 relevant publications for this topic of interest. The clinical areas with publications were the following:

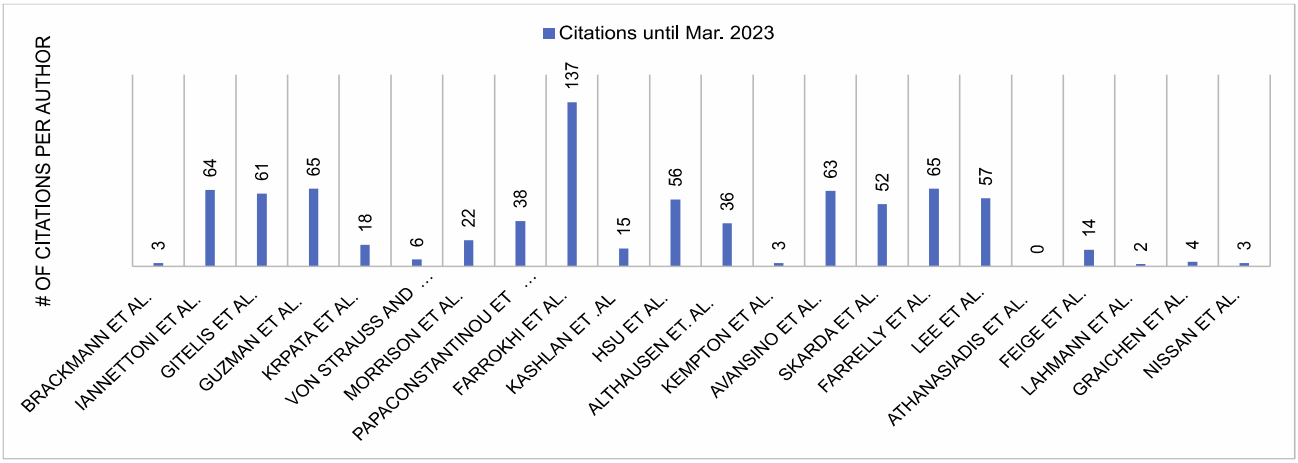
- General proceedings related to surgery and laparoendoscopic surgery: 45%
- Special focus on Orthopedic and Orthopedic Trauma: 18%

- Surgical specialties such as pediatrics, thoracic surgery, neurosurgery, etc.: 23%
- Journals relating to healthcare quality: 5%
- Other Journals: 9%

Thus, the area of general proceedings to surgery and orthopedic have dedicated a higher effort to the subject, compared to subspecialties or other areas such as IT or healthcare quality.

An analysis of citations at PubMed and Google shown in Fig. 2 revealed, that nine identified studies with regard to standardization have been cited more than 50 times, independent of the year of publication [11], [24]–[29]. Whereas only one of the identified studies about digital support systems has been cited 14 times [7] and all others less than five times [8], [30] [31] [32].

F**ig. 2.** Illustrates the number of citations of included publications until March 2023. 9 out of 22 articles have been cited more than 50 times, while 7 studies have been cited less than 10 times.



Results

All 22 identified studies (compare table 2) demonstrated that methods to standardize surgical procedures, instruments, preference cards, or the usage of safety checklists lead to the higher efficiency of intraoperative processes [7], [8], [11], [15], [24]– [41].

15 out of 17 relevant peer-reviewed studies for “standardization” were designed and carried out as observational clinical trials. In contrast, one study has been conducted prospectively, and one was a randomized controlled trial (RCT). Four out of five identified clinical studies about DSS were carried out as retrospective observational trials [7], [8], [30], [31] and one was a prospective observational trial [32]. Only 14% (n=3) were multicenter studies [25], [26], [34], the others were single-center experiences.

Either with or without DSS (or MIS), the results on efficiency were positive. While efficiency improved, in 68% of the studies (n=15), no significant difference in quality was detected (Patient Outcome) [7], [24]–[30], [33],

[35]–[37], [39], [40]. Two single-center studies demonstrated an improvement in quality parameters (length of stay and complication rates) by standardizing surgical procedures [8], [11].

Besides one clinical trial from Switzerland [15], all studies on “Standardization” have been conducted in the USA. Hospital management or medical staff chose 7 different methods to increase the efficiency of intraoperative processes without digital technologies. In 11 clinical studies, instrumentation standardization has been chosen and applied as a single method (n=4) or combined with other methods (n=7). Additional methods included standardizing surgical procedures, preference cards, or pharmaceuticals and creating cost awareness amongst medical staff. 44% of all clinical trials investigated the economic impact of standardizing surgical procedures alone or combined with other interventions (N=8). Overall, the primary surgical areas focused on General & Visceral (G&V) (n=6) and Orthopedic (n=3) surgery.

Five relevant studies investigated the impact of DSS. Three have been conducted in Germany and two in the USA. All of them were carried out in a single-centre approach. In three clinical trials, surgical procedures were standardized and digitally supported by the SPM. In one study, an automated workflow system (AWS), OR-Dashboard, was implemented in the OR. The selected method was the standardization of surgical safety checklists and OR-Time outs. The third selected method was detecting and reducing surgical procedure inefficiencies, supported by a surgical app called Explorer. Two trials focused on Orthopedic, one on G&V and Ear-nose-throat (ENT) surgery, while one did not specify the surgical area.

Table 2. Overview of relevant included studies. The studies are categorized according to their surgical areas and split into selected methods, “Standardization” and “Standardization & Digitalization”.

Standardization							
Surgical area	**Published**	**Author**	**Study Design**	**# of Sites**	**Type of Procedure**	**Country**	**Standardization Methods**
General & Visceral	2002	Brackmann et al.	RCT	Single	Lap. Cholecystectomy	US	Instruments, Surg. procedure
General & Visceral	2011	Iannettoni et al.	Retrosp. obs.	Single	Esophagectomy	US	Surg. procedure
General & Visceral	2015	Gitelis et al.	Retrosp. obs.	Multi	Lap. Cholecystectomy	US	Cost awareness of equipment
General & Visceral	2015	Guzman et al.	Retrosp. obs.	Multi	Lap. Appendectomy	US	Cost awareness of equipment, Instruments
General & Visceral	2016	Krpata et al.	Retrosp. obs.	Multi	Lap. & Open inguinal & abdom. hernia repair	US	Instruments, Surg. procedure
General & Visceral	2018	Von Strauss and Torney et al.	Pros. obs. cohort	Single	Lap. Cholecystectomy	CH	Surg. procedure
Gynecological	2004	Morrison et al.	Retrosp. obs.	Single	Lap. Hysterectomy	US	Surg. Procedure
Mixed	2013	Papaconstantinou et al.	Retrosp. obs	Single	all	US	Surg. safety checklist
Mixed	2013	Farrokhi et al.	Retrosp. obs.	Single	Min. invasive spine, deep brain sim., other subspecialty	US	Instruments
Neurointerventional	2014	Kashlan et .al	Retrosp. obs.	Single	All neurointerventional procedures	US	Instruments, Pref. card, Cost awareness of equipment
Orthopedic	2012	Hsu et al.	Retrosp. obs.	Single	Total knee arthroplasty (TKA)	US	Instruments
Orthopedic	2014	Althausen et. al.	Retros. review	Single	Orthopedic Fractures	US	Specialization, Surg. Procedure
Orthopedic	2020	Kempton et al.	Pros. obs. with retrosp. control data	Single	Partial & Complete articular fractures	US	Instruments
Pediatric	2013	Avansino et al.	Retrosp. analysis and prosp. obs.	Single	Lap Appendectomy	US	Pref. card, Instruments
Pediatric	2015	Skarda et al.	Prosp. obs.	Single	Lap Appendectomy	US	Pref. card, Surg. procedure, Instruments
Pediatric	2017	Farrelly et al.	Prosp. obs.	Single	All	US	Instruments
Plastic	2008	Lee et al.	Prosp. nonrandomized controlled	Single	Breast reconstruction	US	Surg. procedure, Instruments, pharmaceuticals
Standardization and Digitalization							
General & Visceral	2021	Athanasiadis et al.	Prosp. obs.	Single	Lap. RYGB	US	Surg. Procedure
HNO	2017	Feige et al.	Retrosp. obs.	Single	FESS	GER	Surg. procedure
Orthopedics	2020	Lahmann et al.	Retrosp. review	Single	Hip joint	GER	Surg. procedure
Orthopedics	2020	Graichen et al.	Retrosp. review	Single	THA/TKA	GER	Surg. procedure
Mixed	2014	Nissan et al.	Retrosp. review	Single	N/A	US	Surg. Safety Checklist

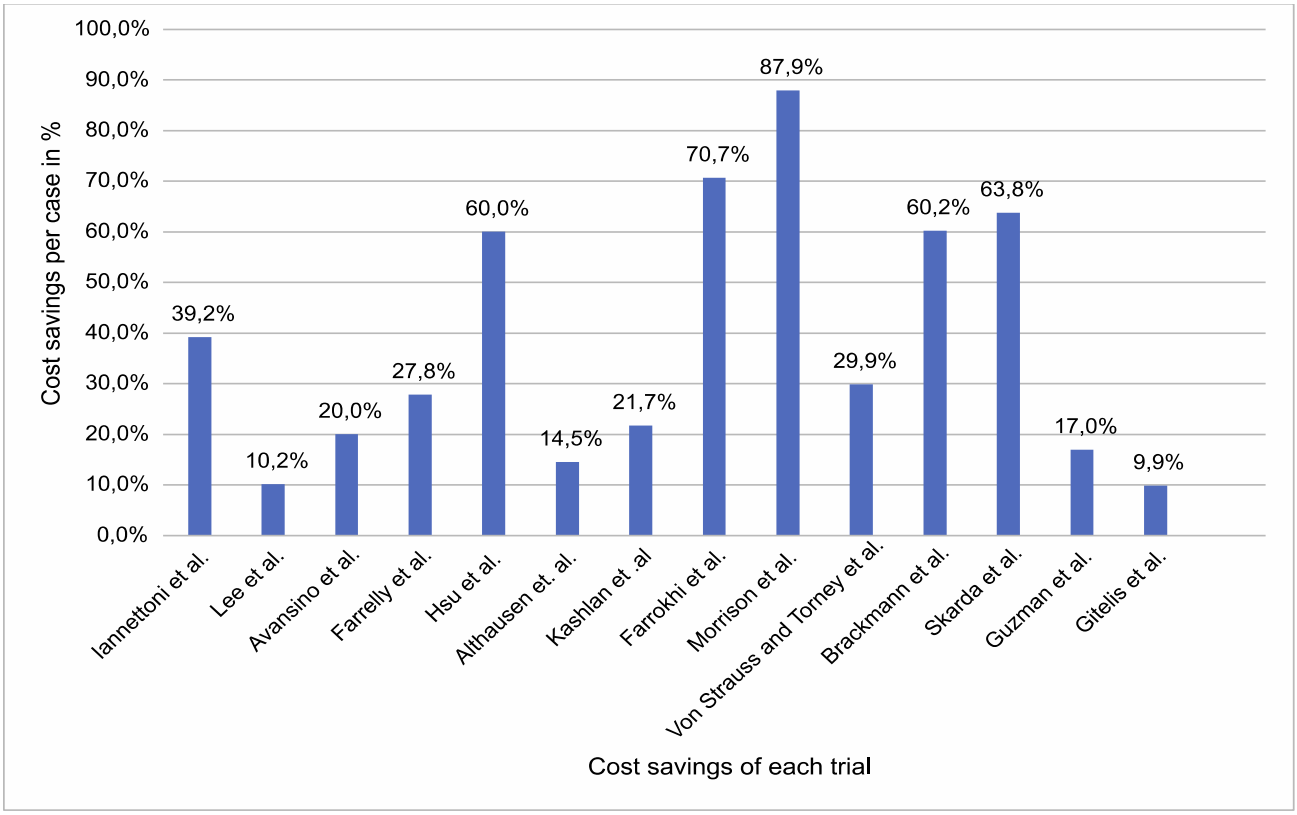
Economic Impact

All studies used institution-specific data to derive and report cost analysis and impact. Values were re-calculated based on the US consumer price index and conversion rates (Euro to USD) of January 2021 to assess the economic impact of all relevant studies.

A significant positive economic impact has been demonstrated in various surgical areas by optimizing intraoperative processes in the OR. Instrument tray standardization, surgical technique modification, preference card establishment and adoption, and cost awareness were the main contributors to reducing costs and improving profitability. In most studies, the parameters to measure efficiency, which transfer into cost savings, were determined to be OR-material (n=14), OR-time (n=4), Re-processing (n=2), or intraoperative complications (n=2). Indirect costs were considered in two studies [29], [38], and all other clinical trials measured direct costs to analyze the economic impact.

The economic impact in absolute dollars showed across all surgical areas cost savings between $70.20 [26] and $3,516 [35] per case. Two studies did not report an absolute dollar value but cost savings per case in percentage [29], [41]. In 14 studies, cost savings in percentage per case have been or could be calculated (compare Fig. 3). Results range between 9,9% [26] and 87,9% [35], and the mean cost savings is 38,1% per case.

Fig. 3. Illustrates the cost savings per case of each clinical trial in %. While the lowest cost savings were reported by Gitelis et al. (9,9%), the highest was demonstrated by Morrison et al. (87,9%).

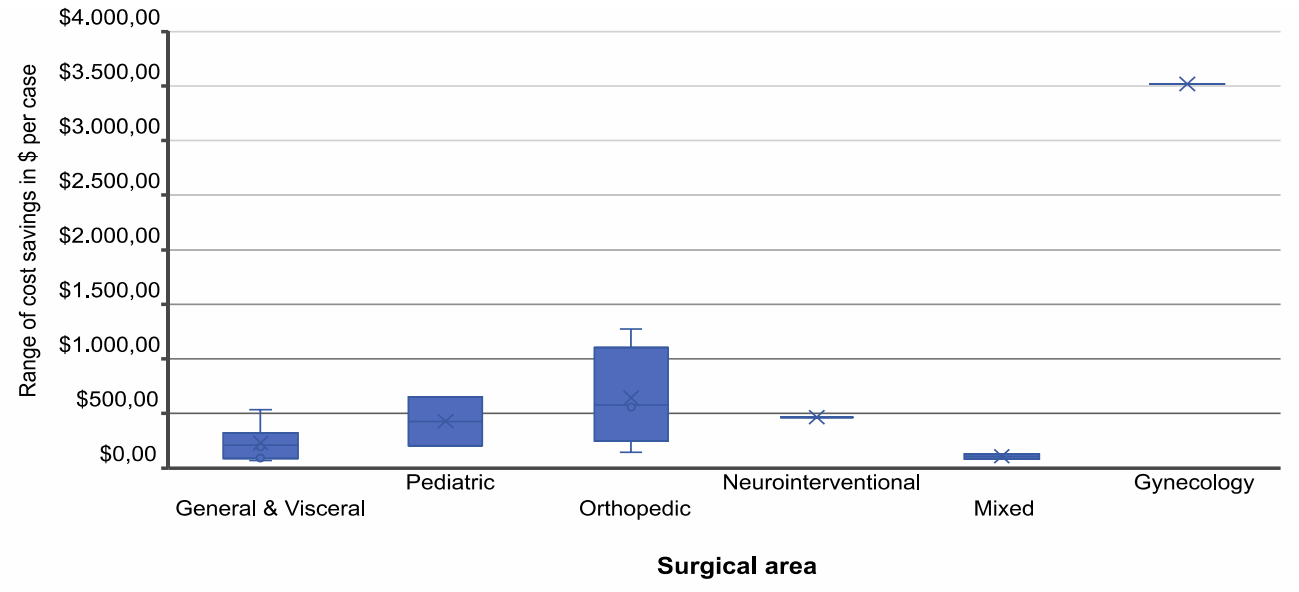


The lowest cost savings per case resulted from general surgeons being educated about the costs of their medical instruments. In a multi-center approach, those physicians who performed laparoscopic cholecystectomies reduced or exchanged costly surgical instruments when they were aware of detailed costs before and after each procedure [26]. Most significant cost reductions per case have been demonstrated in gynecological surgery. Morrison demonstrated in 26 standardized laparoscopic hysterectomy procedures cost savings of $3,516 per case in OR-material. It must be noted that while costs of OR-material were significantly reduced, OR-time increased by 1 h and 20 min per case, but this was not included in the profitability analysis [35].

The range of improvements in profitability generated through standardization in each surgical area is shown in Fig. 4.

The highest cost savings were reported from only one study in gynecology. Notable ranges and mean of cost savings were generally reported from G&V, orthopedics and pediatrics. The lowest mean cost savings are found in studies reporting several different surgical areas, categorized under “mixed”.

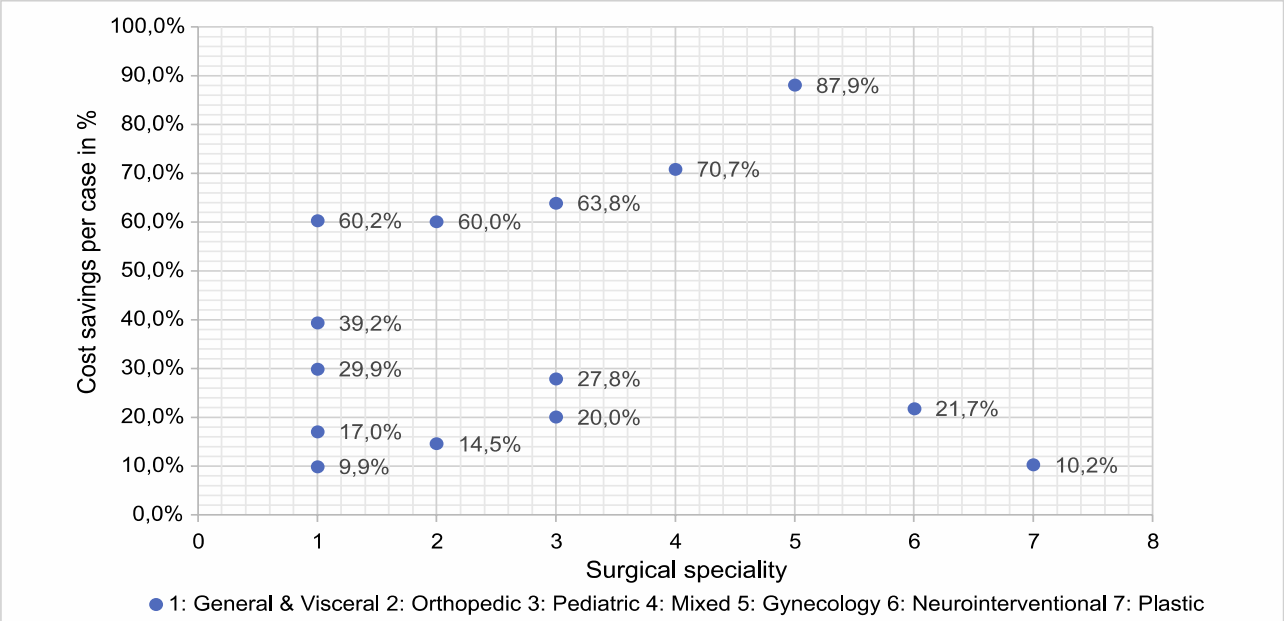
Fig. 4. Range of cost savings per case in $ per surgical area due to standardization.



Six studies, which focused on G&V surgery, demonstrated cost savings ranging between $70,20 and $533,53 and mean cost savings of $227,86. Within those six studies, four different surgical procedures were being researched, laparoscopic cholecystectomy, appendectomy, esophagectomy and laparoscopic and open inguinal and abdominal hernia repair procedures. Transferring optimization of efficiency and thus profitability into improvements in percentage, the results for G&V surgery range between 9,9% and 60,2% per case (compare Fig. 5). However, while improvements based on the parameter of OR-Material lie in the previously

mentioned range, two studies focused on shorter OR-time and lower intra-operative complication rates, resulting in cost savings of 29,9% and 39,2% per case [11], [15]. Orthopedic and pediatric surgery are other surgical areas in which a minimum of three relevant studies were identified. Significant profitability improvements in orthopedics revealed a cost decrease between $145,76 [27] and $1.273,21 [39] per case. Kempton (2020) demonstrated cost savings by instrument standardization at surgically treated tibial plateau fractures ($598,01 and $1.273,21). Otherwise, the broad range of cost savings would be significantly narrower. In percental measurements, methods of intraoperative standardization in orthopedic surgery lead to cost reduction between 14,5% and 60,0% per case [27], [38].

Fig. 5. Impact of Interventions on cost savings per case and surgical area in %. The study in gynecology demonstrated the highest cost savings with 87,9% per case, and one trial in G&V surgery resulted in the lowest cost savings with 9,9% per case.



Considering selected methods, nine studies showed instrument and surgical tray standardization profitability improvements between 10,2% and 70,7% per case. When instrument standardization was chosen as a single method, cost savings ranged between 27,8% and 70,7% [24], [27], [41]. In comparison, six studies included additional methods such as surgical technique modification [29], [40] or standardized implementation of preference cards [28], [37], [40], which led to cost savings between 10,2% to 63,8% per case. In total, eight studies included surgical procedure standardization. Von Strauss and Torney et al. demonstrated through surgical workflow standardization that delays caused by intraoperative micro complications can be reduced by 29,9%. The risk factors associated with the delay were based on the “male gender of the patient, less surgeon experience and intraoperative adhesiolysis”. The reduction resulted in cost savings of 29,9% or $194 per case [15]. Iannettoni et al. also indicated that by modifying surgical workflows of esophagectomies, OR

time could be reduced by 45,7%. The amount of time saved during the intraoperative process resulted in expenditure improvements of 39,2% per case [11]. By standardizing OR-instruments as the second method, 60,2% of OR-material expenditures can be saved [33]. While Lee et al. reported cost reductions of 10,2% per case by additionally standardizing pharmaceuticals during breast reconstructions as the third approach [29], Skarda et al. was able to demonstrate cost savings of 63,8% per case, in pediatric laparoscopic Appendectomies, by adding standardized preference cards [40].

Economic Impact of Digitalization

To optimize intraoperative surgical processes, the positive impact of DSS on efficiency [7], [8], [30]–[32] and quality [8] have been demonstrated in G&V, orthopedic and ENT surgery. The main contributors to increase efficiency are skin to skin time (OR-time) [7], [30], [32], instrumentation reduction, change of instrumentation during the procedure [7], length of stay and recovery room time [8]. Feige et al. demonstrated that standardizing intraoperative surgical workflows 14,3% shorter cutting suture time in ENT surgery (FESS). Also, Athanasiadis et al. reported a reduction of 6% of OR time in bariatric surgery. By providing insights to the OR nurses on items needed and capturing real-time incidents causing delays, the ExplORer App contributed significantly to improving the surgical workflow [32]. With the same digitally supported method as Feige et al., Graichen et al. reported a reduction of 22% of OR time in Orthopedic surgery (Total hip arthroplasty / Total knee arthroplasty). The introduction of the SPM resulted in shorter skin to skin time in another orthopedic case-control trial (mean of 66.71 min with SPM versus 69.11 min without SPM) but was not statistically significant. Instead, a significant reduction in recovery room time (13,7%), postoperative complications (69,9%) and length of stay (18,7%) was reported [8]. Implementing an automated workflow program, OR-Dashboard, improved the compliance of the surgical safety checklist by 4% and the median time-out duration by 18%. Moreover, Nissan et al. reported an additional improvement of 40% in on-time starts of first surgical cases after introducing and adopting this specific DSS [31].

No research has been published on efficiency and quality in other surgical areas, such as thoracic or neurosurgery. Also, an economic analysis has yet to be published to demonstrate the impact of digital support systems on intraoperative surgical workflows.

Results of the research questions

Regarding the conducted results, the stated research questions can be answered beneath.

Research question 1:

In total, 7 different methods were selected for measurement. The primary selected method has been in 65% of the identified research publications, “standardization of instrumentation”, either as a standalone or combined with other methods [24], [25], [27]–[29], [33], [34], [37], [39]–[41]. The second primary method

chosen in 8 out of 17 included articles has been „standardization of the surgical procedure“ [11], [15], [29], [33]–[35], [38], [40], followed by „creation of cost awareness“ (n=3) [25], [26], [37], „standardization of preference card“ (n=3) [28], [37], [40], „surgical safety checklist“ [36], „standardization of pharmaceuticals“ [29] and „specialization“ [38].

Research question 2:

All 17 identified articles demonstrated a significant positive economic impact, resulting in cost savings ranging between $70.20 [26] and $3,516 [35] per case. Transferred into percentage savings per case, in 14 out of 17 clinical trials (excluding Krpata et al., Papaconstantinou et al. and Kempton et al.), savings range between 9,9% [26] and 87,6% [35].

Research question 3:

The main parameter selected has been OR-Material (n=10) [25], [26], [28], [33]–[35], [38]–[41].

Alternatively, combined with the parameters of re-processing costs [24], [27] and OR-time [36]. OR-time in combination with either intraoperative complications [11], [15] or supply waste [29] has been the second main parameter.

Research question 4:

Several different DSS have been developed to generate, display, analyze and use data from intraoperative surgical workflows. [42]–[48] However, research showing an impact on efficiency and quality of intraoperative surgical processes and eventually its standardization is limited to three surgical workflow management systems, ExplORer [32], and OR-Dashboard [31] and SPM [7], [8], [30].

Research question 5:

Research has shown that DSS has a significant positive impact on efficiency by reducing the skin to skin time (14.3%) [7] OR time (6% and 22%) [30], [32], recovery room time (13.7%), length of stay (18.7%) [8] and time-out duration (18%) paired with surgical safety checklist compliance [31]. Furthermore, a positive impact on quality by reducing the postoperative complication rate by 69.9% has been demonstrated [8].

Research question 6:

No research could be identified to demonstrate the economic impact of DSS on intraoperative surgical processes.

Discussion

All studies without DSS reported cost savings in the intraoperative process. Comparing relevant studies with each other, material costs vary significantly across different surgical areas and specific procedures. Laparoscopic cholecystectomies or appendectomies are not as complex, and the OR material costs are

relatively low compared to laparoscopic hysterectomies, or surgically treated tibial plateau fracture. To compare each study's economic impact on profitability, only cost savings per case in percentage should be considered. Five studies reported cost savings of 60% and more per case from various surgical areas [24], [27], [33], [35], [40]. Improvements were achieved through instrument standardization or in combination with surgical technique modifications [33], [35] and preference card standardization [40]. Only Morrison et al. reported a cost analysis on re-processing [35]. Since studies have been differently designed within the same surgical area, drawing correlations seems challenging. Research about the profitability impact of standardization and digitalization on complex, time- and material-intensive procedures in G&V, as well as pediatric surgery, have yet to be published. However, complex procedures, such as Roux-en-Y gastric bypass (RYGB) in bariatric surgery, have already been the focus of hospital management and medical staff. Aird et al. demonstrated in a multi-center approach that standardization (pre-, peri- and postoperative) of bariatric procedures, predominantly RYGB (89,2%), led to a reduction of intraoperative complications from 4.1% to 0.6% over a period of four years. This study indicates that standardization of intraoperative RYGB workflows positively impacts the quality and, thus, efficiency due to less delay in time caused by complications. In addition, the three-month postoperative complication rates dropped significantly from 20.2% to 13.2%. Because the study's design and interventions happened simultaneously, the most effective interventions could not be measured [49]. These findings can be related to Athanasiadis et al., who reported an increase in efficiency in RYGB with the introduction of the Explorer App [32], [50]. Further research of a combined approach will be necessary to analyze potential extra benefits and to reveal its economic relevance.

The SLR demonstrated that integrating DSS can significantly impact efficiency and quality positively. It can be assumed that shorter skin to skin time [7], [30] or OR time [30], [32] will have a significant positive impact on hospitals' profitability. However, the level of influence can hardly be estimated, as relevant studies with or without DSS strongly differed by design or country.

The latest research on DSS of surgical workflow recognition, prediction, and context awareness shows promising potential to optimize standardized intraoperative workflows further. Khan et al. successfully demonstrated machine learning (ML) techniques to provide workflow analysis of surgical videos in pituitary surgery automatically. The DSS, "Touch Surgery", was implemented, which achieved an accurate recognition of the surgical phases (91% accuracy) and steps (76% accuracy) [51]. In addition, Garrow et al. confirmed in a systematic review that ML for surgical phase recognition can be performed with high accuracy. The research emphasized that the accuracy depends on the model, data type and complexity of the surgical procedure. This might explain the high number of studies which chose lap. Cholecystectomy as investigated procedure [44] Another review of recognition systems on intraoperative processes by Junger et al. concluded that using different methods resulted in above 90% recognition accuracy [52]. Most publications revealed that video

data was focused on recognizing situations and simple, standardized procedures. Also, attention was drawn towards the feasibility and implications of surgical workflow variability. This focus led to very few publications, which included the adaptability and transferability of the different recognition systems [52]

In summary, recent accomplishments of DSS for workflow recognition and prediction could provide additional data for improved clinical and administrative decision-making and education purposes. This includes enhanced opportunities to increase efficiency and improve quality by continuously adapting standardized surgical workflows. Even though technical challenges exist due to surgical variability, the continuing trend towards standardizing complex surgical procedures [53]–[55] might accelerate systems adaptability and transferability.

As DSS's potential economic and medical benefits on intraoperative workflows have yet to be researched, more scientific research will be needed.

Limitations of the study

This systematic literature review has several limitations. In most studies, costs for OR equipment were chosen as the only parameter to demonstrate the economic impact. Instrument costs were in many studies pulled from the hospital system, which did not provide individual usage tracking. Apart from three studies, all clinical studies were single-center designs and thus relied on a cost analysis based on each cost structure regarding supplier agreements and personnel. The seclusion of essential details of the cost analysis made it impossible to draw correlations, or plausible conclusions, about general cost structures. None of the studies reported impacts on indirect costs besides Lee et al., who did not publish the result in absolute dollar value but in percentages per case [29]. Another limitation of this review is the focus on the economic impact of intraoperative processes. Several other cost drivers exist in the OR before and after the procedure itself. This focus on intraoperative workflow standardization and its impact on efficiency and quality limits the scope and available literature on DSS. Digital solutions in anaesthesia, such as Real Time Locating Systems, have already shown a positive impact on efficiency (OR-time) [56], as well as real-time decision support systems demonstrated significant cost savings through waste reduction and billing charge captures [57] but were excluded for this review.

Conclusion

This literature review indicates that standardization of intraoperative workflows contributes significantly to cost reductions within the OR. Selected standardization methods improve the hospital's financial situation and overcome the economic burden. More research on standalone methods applied, such as surgical workflow standardization or education on cost awareness, will be needed to draw different correlations and underline each method's effectiveness in other major surgical areas to improve the economic situation.

Only two studies demonstrated significant cost reductions by decreased intraoperative complication rates in G&V surgery and instrument re-processing in orthopedics (TKA). Further research on these parameters in other surgical areas is still needed to support the findings. The economic impact has primarily been measured on surgical procedures in general & visceral and orthopedic surgery. Complex procedures, which require advanced skillsets and account for significant operational costs, have infrequently been included. From a hospital management perspective, further research will be needed to understand if standardization methods can have an even higher economic impact on complex and costly procedures in specialties, such as Bariatric or Hepato-Pancreato-Biliary surgery.

First studies of DSS also demonstrate additional positive influences on intraoperative surgical workflow efficiency in ENT, G&V and Orthopedics. However, research is limited to prospective and retrospective observations and surgical areas and lacks its contribution to direct and indirect costs. Further research on efficiency and quality transferring into significant cost reductions is required to demonstrate the economic impact and accelerate MIS integration for intraoperative surgical processes within the hospital landscape. Additionally, research on complex and costly procedures in general & visceral surgery and the economic impact of collected healthcare data during surgical procedures by DSS in workflow recognition and prediction is needed. This will contribute to hospital management's perception of the value of investments in digital solutions for economic and patient outcome purposes.

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5.3 Article 3: Impact of a digitized workflow for knee endoprothesis implantations on hospital specific ratios

Title:	Impact of a digitized workflow for knee endoprothesis implantations on hospital-specific ratios
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Journal:	Journal of Technology and Healthcare von Schudnat, C., Lahmann, B., Schoeneberg, K. P., Albors-Garrigos, J., & De-Miguel-Molina, M. (2023). Impact of a digitized workflow for knee endoprothesis implantations on hospital-specific ratios. *Technology and Health Care*, (Preprint), 1-14. https://content.iospress.com/articles/technology-and-health-care/thc220395
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Abstract

Background

The continuous decrease of healthcare resources requires hospitals to improve efficiency while striving to improve quality standards that deliver better patient outcomes.

Objective

The objective of this study was to analyze if the implementation of digital support systems during orthopedic surgery positively affected clinical processes and quality ratios.

Methods

A retrospective case-control study of 297 knee joint replacement procedures was conducted between 2015 and 2020. Thirty-five patients were allocated to the treatment and control groups after they were identified with exact matching and estimation of the propensity score. Both groups were balanced regarding the selected covariates. The effect of the surgical procedure manager (SPM) on the incidence of acute haemorrhagic anaemia between the two groups was evaluated with a t-test, and the odds ratio was calculated.

Results

SPM-supported surgery has no significant influence on the incidence of acute haemorrhagic anaemia but leads to significantly shorter hospital stay (1.93 days), changeover (4.14 minutes) and recovery room time (20.20 minutes). In addition, it reduces the standard deviation of operation room times.

Conclusions

The study concludes that SPM enhances surgical efficiency and maintains quality outcomes. To overcome their increasing financial pressure hospital management should commercially evaluate the implementation of digital support systems.

Keywords: quality improvement, efficiency, operating rooms, the standard of care, digital technology, Surgical Procedure Manager

JEL Classification: C12, I15, L15.

1. INTRODUCTION

The European health systems and hospital services are facing increasing competitive pressures due to increasing privatization and reduction of investments from local governments [1-2]. Health care reforms across multiple European countries, in accordance with the principles of the Diagnosis Related Groups (DRGs) introduced in early 2000, means that hospitals are funded according to case type, rather than reimbursed for expenditure [3-7]. Importantly the implementation of DRG varies across Europe. Serden et al. demonstrated that amongst 11 European countries the categorization of inguinal hernia repair varies in important aspects such as available DRG's (open and laparoscopic), day case rates, coding depth, or the inclusion of capital costs [4].

Additionally, countries like Germany introduced the Hospital Structure Act (2016), which focuses on high-quality and patient-centered healthcare. The Act expect the Hospitals to perform a minimum of specific procedures to maintain the accreditation. It also includes financial incentives linked to performance [8].

Based on this legal framework, public and private hospitals must establish a management and control system based on economic principles, while delivering high-quality patient care despite limited resources. In order to be successful in the health care market, many hospitals react to these economic and quality pressures with a variety of optimization methods [9,10].

According to the Hospital Structure Act, allowances and fee reductions are granted, if the quality and process standards set by the Institute for Quality Assurance and Transparency in Health Care are met. This enables health insurance to reduce funding/payments to poor quality providers and increase funding to high quality [8,11].

Each hospital quality management has the duty to implement the appropriate legal requirements [12-13]. In addition, it should aim to create a virtuous cycle of constant improvement through planning, guidance, and control [9]. Different quality management tools are used in isolation or combinations to meet legal requirement and ensure a constant drive towards higher quality [5,14].

The way care is delivered in a hospital depends on the coordination of personnel, material, and established treatment methods. In the DRG system, process management requires the continuous reflection on, and adjustment of, existing processes service provision. Continuous oversight should lead to cost reductions, sustainable revenue increases, and quality improvement. An analysis of the core processes across all cost centers that provide treatment in a hospital treatment shows whether revenues are sufficient to cover expenses [15].

Process management involves planning, controlling, and organizing measures to monitor the value chain in the context of time, costs, quality, and customer satisfaction. The aim of the analysis is to identify possible improvements, through optimization and standardization [16,17]. The standardization of clinical pathways can

increase safety and quality of care as experienced by the patient and drive effectiveness and efficiency for the healthcare provider [18-20].

In surgical departments, the main treatment and up to 40% of the total costs occur in the operating room. In order to evaluate efficiency of operating room processes and compare them with different treatment methods or new workflows, certain relevant, detailed, and comparable ratios must be defined [6,21]. Reducing process times, including cutting-suture, postprocessing, and changeover time, is critical to increasing efficiency and quality in the operating room. Reducing surgical complications may reduce the length of the postoperative hospital stay [6,9,22,23].

Efficiency management studies have documented improved efficiency through the rationalization and standardization of surgical processes [24,25]. The evaluation of standardized surgical procedures addresses improvements in both efficiency and quality in surgical practice [26,27]. Surgical workflows offer particular potential for standardization and optimization because establishing quality and process standards reduce failure rates and processing times, which can increase the utilization of operating rooms [28].

The standardization and quality management of perioperative clinical pathways based on digital technologies has been a long-term focus of medical research and development [29]. Automated programs guide the surgeon through the operation using a defined digital workflow based on surgical process models. A software solution that focuses on the workflow based digitization of perioperative processes is called the Surgical Procedure Manager (SPM) [30,31].

Few published studies examine the effects of digital workflows using SPM on efficiency and quality in the operating room. Due to the limited sample size and the specificity inherent in different specialties and operations, analysis can identify trends. However, it cannot extrapolate the results to other surgical procedures without restrictions [25,32-34].

Research gap and objective

Several publications on intraoperative standardization of processes as a quality management approach clearly show various positive effects on the quality of surgical outcome, perioperative efficiency, and employee satisfaction [35-37].

Other studies prove that the effects of clinical and perioperative process standardization have positive economic effects from the perspective of hospital management [38-41]. However, a small number of studies address the effects of digitizing standardized surgical processes. The two most important studies currently available in the literature show a positive trend for intraoperative clinical effects of digital support systems [25,32]. However, neither Graichen's nor Feige's findings can be applied to every surgical procedure. For example, the differences in anatomy and clinical settings can limit the generalizability of the findings. A different study design is needed to assess the transferability of the results to other surgical procedures and specialties.

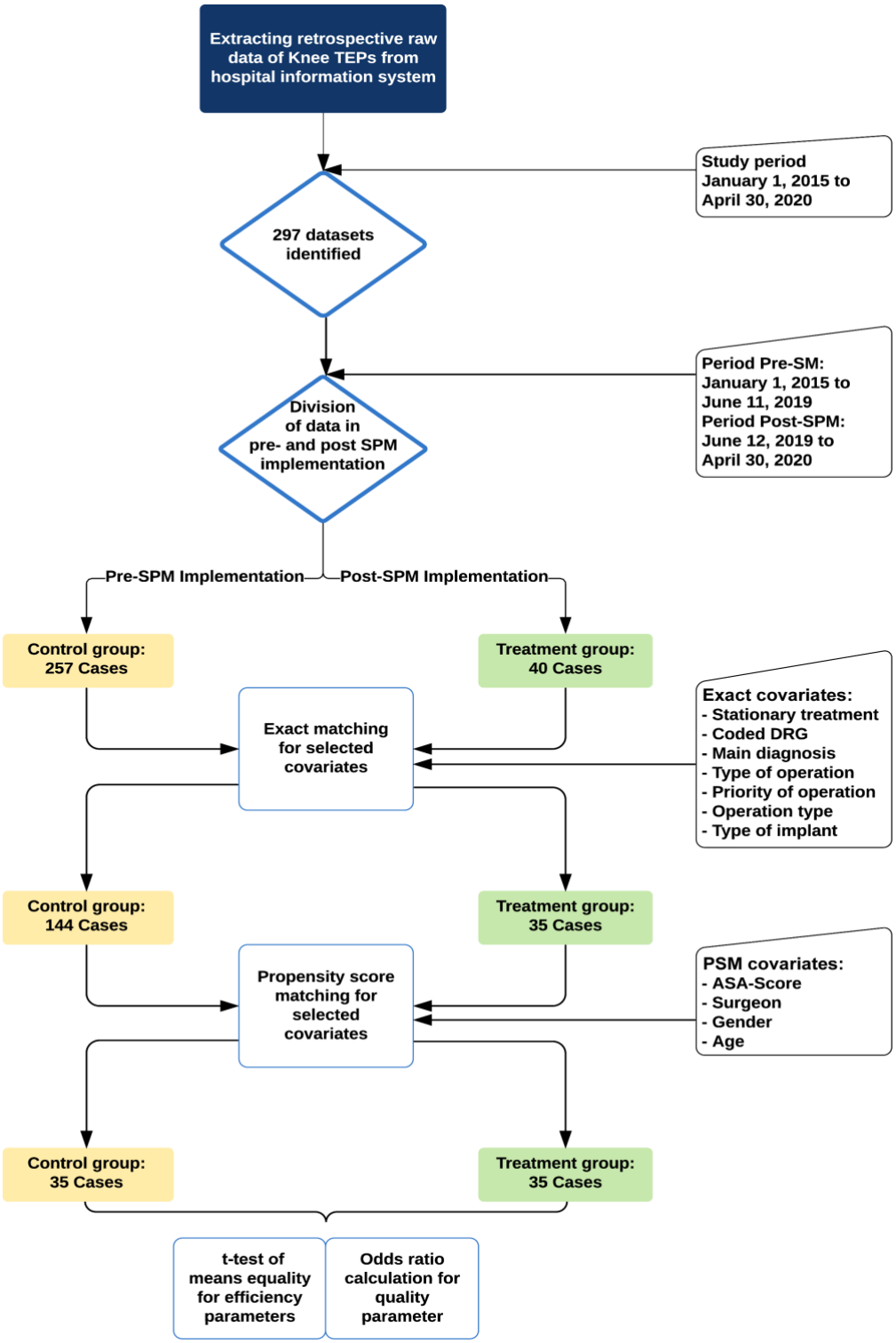
Based on these findings, the study's main objective was to evaluate whether the standardization of surgical workflows by the SPM improves the quality and efficiency parameters of knee arthroplasty implantations. This objective led to the following research question: Do perioperative digital support systems positively affect selected clinical processes and quality ratios in orthopedics?

2. METHODS

2.1 Study Procedure

This study is based on a raw data set of 297 knee joint replacement procedures (OPS-Code: 5-822) performed at a German hospital between January 1, 2015, and April 30, 2020. Conventional surgery not guided by SPM was performed until June 12, 2019, at which point SPM was installed and used by the surgical team in the subsequent knee joint replacement procedures. The dataset contained 257 surgeries performed before the SPM software was implemented (control group) and 40 surgeries performed after SPM implementation (post SPM or treatment group). The detailed flow chart shown in Fig. 1 illustrates the study procedure.

Fig. 1: Flowchart describing the patient selection methodology for a study comparing Surgical Procedure Manager (SPM) supported knee joint replacement procedures (treatment group) with knee joint replacement procedures not supported by SPM (control group).



The surgical team developed the SPM-based surgical pathway by standardizing their procedures into a digital workflow. The agreed workflow can reduce unwanted deviations and quality as a quality improvement

initiative. The workflow includes all the steps to be followed except in cases of extraordinary events that, by definition, are difficult to standardize. The data collected for all procedures correspond between the control and treatment groups. Data and control parameters used for the subsequent analysis are summarized in Table 1.

Table 1: Evaluated data and control parameters used to prepare the dataset to perform propensity score matching prior to analysis.

Description	**Study design**	**Parameter code**	**Type**
Clear Difference between control and treatment group	Utilization of SPM	Yes/no	Binary
Stationary or ambulant	Stationary	Yes/no	Binary
Age at operation	Age > 45 and < 91	Numeric	Numeric
ASA risk classification (ASA score)	1, 2, 3	Numeric	Numeric
Coded DRG	DRG I44B & I44C	Yes/no	Binary
Main diagnosis	ICD M17.1 Gonarthrosis	Yes/no	Binary
Type of operation	OPS 5-822	Yes/no	Binary
Code of surgeon	Surgeon 1, Surgeon 2, Surgeon 3	Ordinary	Nominal
Code of priority of surgery	Planned	Yes/no	Binary
Code of operation time	During regular OR time	Yes/no	Binary
Type of implant	Supplier: Stryker	Yes/no	Binary
Cutting-suture time	Time from cut to suture	Minutes	Numeric
Preparation of the operating room after surgery	Postprocessing time	Minutes	Numeric
Preparation of the patient before surgery	Patient preparation time	Minutes	Numeric
Total turnover time	Duration entering and exiting from OR	Minutes	Numeric
Changeover time	Duration from finishing an operation till the start of the following operation within regular OR time	Minutes	Numeric

SPM, Surgical Procedure Manager; ASA, American Society of Anesthesiology; DRG, Diagnosis Related Group; ICD, International classification of diseases; OPS, Operation and procedure key; OR, Operating room

The codes in the table are assigned to prepare the dataset and to perform the pretest propensity score matching (PSM) to balance the covariates of the groups. After the pretest PSM matched the chosen covariates (ASA score, surgeon, age and gender), the final data set contained 70 patients, of whom 35 were in the control group operated before SPM implementation, and 35 were in the treatment group and operated after SPM implementation. Twenty-seven datasets were deleted because of partially missing information.

2.2 **Statistical Analysis**

Statistical analysis was done using SPSS 27 for MacBook Pro 64-Bit Version. Because the group of 40 patients treated with SPM-supported surgery is significantly smaller than the group of 257 patients treated without SPM support, the PSM test compared the covariates among covariate-matched individuals between the two groups. The PSM test compared the distribution of results for the matched groups to the entire data set. Because the SPM and non-SPM samples were already defined and the implementation date for SPM was known, randomization and double-blind implementation were not feasible [42].

Assumptions of normality were tested using QQ plots, which showed normal distribution of the analyzed data. Variance homogeneity was tested and confirmed using the Levene test. A t-test of means equality was conducted to assess whether the group of patients with SPM support and without SPM support differed in efficiency parameters [43].

Considering the binary scaling of the quality target parameters and the data were based on a case-control study, the odds ratio (OR) for developing a D62 acute hemorrhagic anaemia complication was calculated. An OR value greater than 1 indicated that the measured complication appeared more often in the SPM-supported group than in the group not supported by SPM. The percentage value could be calculated based on 1-OR, or the reciprocal OR could be calculated with 1/OR if the confidence interval for the OR included 1, the calculated OR was not considered statistically significant. If the OR did not include 1, the result was considered statistically significant [44,45].

3. RESULTS

The following covariates were matched between the control group and the treatment group. As a first step, this matching resulted in a control group of 144 patients, which corresponded precisely to the control group regarding the aforementioned covariates. Therefore, no PSM was necessary: Stationary treatment, coded DRG, main diagnosis M17.1 gonarthrotic, type of operation, the priority of surgery, operation time, and type of implant. Table 2 shows the frequencies of the covariates after exact matching and before PSM.

Table 2: Frequencies of evaluated data after exact matching before propensity score matching.

	Parameter/Covariates	Frequency	Percent	Valid Percent	Cumulative Percent
Utilization of SPM	no-SPM	144	80.4	80.4	80.4
	SPM	35	19.6	19.6	100.0
Case type	stationary	179	100.0	100.0	100.0
Coded DRG	I44B	179	100.0	100.0	100.0
Main diagnosis	M17 Gonarthrosis	179	100.0	100.0	100.0
Type of operation	OPS 5-822	179	100.0	100.0	100.0
Priority of surgery	Planned	179	100.0	100.0	100.0
Operation time	During regular OR time	179	100.0	100.0	100.0
Type of implant	Supplier: Stryker	179	100.0	100.0	100.0
Gender	Male	66	36.9	36.9	36.9
	Female	113	63.1	63.1	100.0
ASA score	1	12	67.0	67.0	67.0
	2	60	33.5	33.5	40.2
	3	107	59.8	59.8	100.0
Surgeon	Surgeon 1	61	34.1	34.1	34.1
	Surgeon 2	63	35.2	35.2	69.3
	Surgeon 3	55	30.7	30.7	100.0

SPM, Surgical Procedure Manager; OR, Operating room

The gender, ASA score, surgeon, and age covariates showed several different characteristics and did not correspond in their distribution between the control and treatment groups. The descriptive statistics by ASA score, surgeon, and gender after PSM (Tables 3-5) showed that the distribution of these covariates in the pre-match control group differed before matching.

Table 3: Table of frequencies of American Society of Anesthesiology (ASA) score after propensity score matching.

ASA score of patient		Frequency	Percent
no-SPM pre-Match	1	8	5.6
	2	50	34.7
	3	86	59.7
	Total	144	100.0
SPM	1	4	11.4
	2	10	28.6
	3	21	60.0
	Total	35	100.0
no-SPM post-Match	1	3	8.6
	2	13	37.1
	3	19	54.3
	Total	35	100.0

SPM, Surgical Procedure Manager

Table 4: Table of frequencies of surgeon after propensity score matching.

Surgeon		Frequency	Percent
no-SPM pre-Match	Surgeon 1	47	32.6
	Surgeon 2	53	36.8
	Surgeon 3	44	30.6
	Total	144	100.0
SPM	Surgeon 1	14	40.0
	Surgeon 2	10	28.6
	Surgeon 3	11	31.4
	Total	35	100.0
no-SPM post-Match	Surgeon 1	11	31.4
	Surgeon 2	10	28.6
	Surgeon 3	14	40.0
	Total	35	100.0

SPM, Surgical Procedure Manager

Table 5: Table of frequencies of gender after propensity score matching.

Gender		Frequency	Percent
no-SPM pre-Match	Male	54	37.5
	Female	90	62.5
	Total	144	100.0
SPM	Male	12	34.3
	Female	23	65.7
	Total	35	100.0
no-SPM post-Match	Male	10	28.6
	Female	25	71.4
	Total	35	100.0

SPM, Surgical Procedure Manager

Table 6: Efficiency targets

Efficiency targets		N	Mean	Std. Deviation	Minimum	Maximum
Cutting-suture time [min]	no-SPM	35	67.60	9.94	45	93
	SPM	35	66.37	6.85	54	88
Patient preparation time [min]	no-SPM	35	36.91	9.92	20	67
	SPM	35	37.71	8.48	23	65
Total turnover time [min]	no-SPM	35	114.86	15.83	68	140
	SPM	35	115.94	10.99	100	150
Recovery room time [min]	no-SPM	35	116.86	36.68	45	250
	SPM	35	96.66	22.92	60	155
Changeover time [min]	no-SPM	35	40.57	14.393	25	50
	SPM	35	36.43	4.161	26	34
Hospital stay time [days]	no-SPM	35	10.13	3.45	5.11	20.89
	SPM	35	8.20	3.24	3.16	17.56

SPM, Surgical Procedure Manager

Covariate age matching was performed, so the groups had a similar age structure. Figure 2 shows the control group's age distribution compared to the treatment group's age distribution before PSM. The mean age in the control group was 70.99 years compared to 66.83 years in the treatment group. Figure 3 shows the control group's age distribution compared to the treatment group's age distribution after PSM. The mean age in the control group decreased to 66.94 years compared to 66.83 years in the treatment group.

Fig. 2. Age distribution in the control and treatment group before propensity score matching. SPM, Surgical Procedure Manager

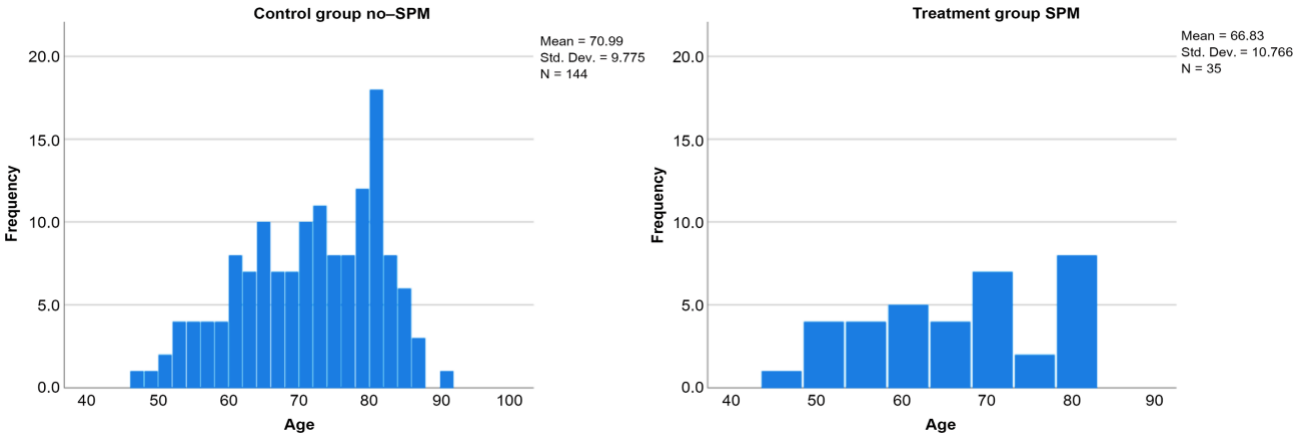
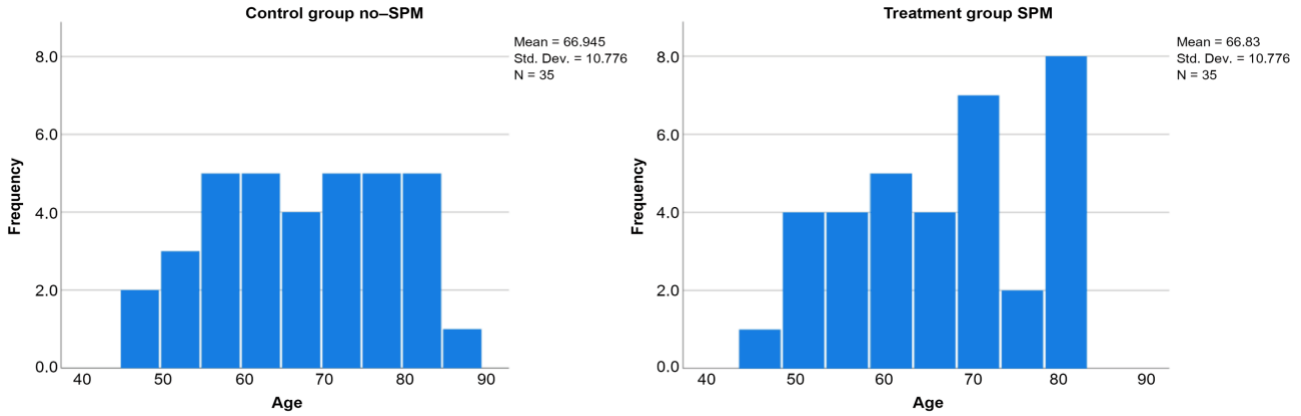


Fig. 3: Age distribution in the control and treatment group after propensity score matching. SPM, Surgical Procedure Manager.



After exact matching and PSM, the control and treatment groups were very similar in the matching covariates, reducing the probability of biased results due to different covariate structures.

An analysis of the descriptive statistics (Table 6) showed that recovery room time, changeover time, and hospital stay time were reduced in the treatment group. The times for the remaining covariates were either not reduced or reduced by a minimal amount. Furthermore, the standard deviation (SD) for some efficiency parameters was lower in the treatment group compared to the control group. The SD of cutting-suture time is reduced by 3.09 minutes, the SD of total turnover time by 4.84 minutes, the SD of recovery room time by 13.76 minutes, and the SD of changeover time by 10.23 minutes.

Equality of variances was tested and confirmed by the Levene test. After testing the assumptions, a t-test of means equality was calculated. Table 7 shows that SPM-supported interventions significantly differ from

interventions not supported by SPM for the covariates of recovery room time, changeover time, and hospital stay time. There were no significant differences between the groups regarding operation times, according to the t-test. The duration of recovery room time was significantly shorter for SPM-supported patients (96.66 minutes compared to 116.86 minutes without SPM). Changeover time was significantly shorter for SPM-supported patients (36.43 minutes compared to 40.57 minutes without SPM). Hospital stay time was significantly shorter for SPM-supported patients (8.20 days compared to 10.13 days without SPM).

Table 7: Result t-test of means equality of efficiency parameters differentiating by Surgical Procedure Manager (SPM) and non-SPM P values

Efficiency targets	**mean no-SPM**	**mean SPM**	**p-value**
Cutting-suture time [min]	67.60	66.37	0.549
Patient preparation time [min]	36.91	37.71	0.718
Total turnover time [min]	114.86	115.94	0.74
Recovery room time [min]	116.86	96.66	0.007
Changeover time [min]	40.57	36.43	0.003
Hospital stay time [days]	10.13	8.20	0.018

SPM, Surgical Procedure Manager

Table 8: Cross table of diagnosis of D62 acute hemorrhagic anemia in the control group (no-SPM) and treatment group (SPM).

Quality targets	**no-SPM**	**SPM**	**Total**
Count D62(no)	26	29	55
% within Diagnosis D62	47.30%	52.70%	100.00%
Count D62(yes)	9	6	15
% within Diagnosis D62	60.00%	40.00%	100.00%
Count D62(sum no & yes)	35	35	70
% within Diagnosis D62	50.00%	50.00%	100.00%

SPM, Surgical Procedure Manager

Table 9: Odds ratio for the occurrence of D62 hemorrhagic anemia in the control group and treatment group.

	Value	95% Confidence Interval	
		Lower	Upper
Odds Ratio for Diagnosis D62	0.598	0.187	1.908
For cohort Data no-SPM	1.318	0.676	2.572
N of Valid Cases	70		

SPM, Surgical Procedure Manager

The OR examined whether the treatment and control subsamples differed in the quality parameter D62 acute hemorrhagic anaemia. Table 8 shows the cross table of frequencies for diagnosing D62 acute hemorrhagic anaemia. With 35 patients each in the SPM-supported and non-SPM groups, Table 8 demonstrates that D62 was diagnosed in the SPM-supported group 6 times and in the non-SPM group 9 times. Table 9 demonstrates that the OR for D62 is 0.589, which implies that the chance for the occurrence of D62 is 40.2% lower in the SPM-supported group or 1.318 times higher in the non-SPM group. The confidence interval for the OR included one, so the calculated OR was not considered statistically significant.

4. DISCUSSION

The results of this study show that the application of digital workflow support software for knee joint replacement procedures significantly reduced the changeover time, hospital stay time, and recovery room time but did not influence different operation times. In addition, the SDS of cutting-suture time, total turnover time, changeover time, and recovery room time were reduced, representing added value regarding theatre utilization because processes with low SDs can be better planned. No significant effects could be confirmed for the quality parameter D62 acute hemorrhagic anaemia. The research question was answered by showing that the SPM in this study significantly affects knee replacement procedures regarding selected efficiency ratios. However, no significant effect was demonstrated regarding quality ratios.

After successful PSM, the control and treatment groups were broadly comparable concerning the selected covariates. If a prospective randomized study cannot be conducted, as in this case, then statistical methods such as matching by estimating the PSMs using a logit model should be done to try to increase internal validity by balancing the groups according to their characteristics. This fact reduces the effect of confounding factors, allowing the observed effects to be derived with a higher probability than the treatment outcome. However, because retrospective clinical case-control data are used, it is impossible to balance all confounding factors between the groups as there may be unknown influencing factors; i.e. there remains a risk that the observed effects were not caused by the treatment but by other factors. In addition, the interpretation should consider

that in smaller samples, excluding patients in the control group who cannot be matched to a partner in the treatment group may result in a loss of statistical power [43,46-49].

Optimizing process efficiency positively affects economic performance, quality of healthcare, and health outcomes [25,32,44,45]. The efficiency and quality effects of digital workflow support systems in the operating room during surgery have not been sufficiently researched. The observed effect of reducing the hospital stay time through the use of digital support systems in the operating room can be considered an initiative that improves efficiency for the hospital and the quality of care for patients. In this specific context (German hospitals with required legal quality assurance in place), digital workflow support systems can positively influence the quality and efficiency of hospital-based treatment of patients requiring a knee joint implant.

There are some limitations to this study. The data were collected from the orthopedic department of an average German hospital, thus limiting the results to orthopedic patients. The results only concern knee replacement procedures and cannot be transferred indiscriminately to other types of surgical procedures. The sample of 40 SPM-supported operations collected in a single hospital between 2019 and 2020 is small and thus may not be representative of other hospitals due to unknown bias. Additional research into the application of digital support systems in surgical practice from other hospitals and other disciplines is needed to improve the scientific understanding of this promising interdisciplinary technology. Since surgical workflows depend on the training and experience of medical staff and clinical infrastructure, clinical results can be transferred to other countries with a similarly high level of health care, such as the Netherlands, Japan and Norway.

Other sources considering the problem analyzed in this study discuss the general approach to digitization in medical care and show whether and why digitalization is relevant in the healthcare sector.

Following the European Commission approach and the importance of effectivity and economic side assessment, the impact of digitization of healthcare is expected to be more profound in the future than in the past. The commission provides recommendations that address the fact that digital transformation will substantially change healthcare systems' future. The commission recommends evaluating the impact of digital health services and that decisions about the adoption, use, or reimbursement of new digital health services should be based on evidence of their performance against healthcare system objectives. Before implementation, new digital health services should be judged based on broad medical health objectives such as quality, accessibility, efficiency and equity. Hospital decision-makers should be progressive but cautiously, develop a digital transformation strategy, and create an environment willing to adopt evidence-based innovations [50,51].

Additional sources are also consistent with these recommendations of the European Commission and the approach and results of the study performed in this paper. Reports of the Swedish Government's Expert Group on Public Economics and World Economic Forum show great benefits from better utilizing digital technology

in healthcare. Digital transformation in healthcare is ongoing rapidly, bridging the gap between the digital and physical worlds. Digitalization is supporting and accelerating the systemic shift to value-based healthcare. Most studies of the reports indicate either significant quality improvements or cost savings, and sometimes both. Digitization has led to significant changes in several established industries, creating new players at the cost of those who have remained stuck to outdated forms of organization. Healthcare is highly differentiated from other industries, but new forms of tension are emerging in healthcare demand and reimbursement systems as they digitize. Without reforms to ensure that digitization benefits - its network and scale effects - are realized, these tensions will continue to grow. Therefore, necessary health policy framework conditions should be created to advance the digital transformation [52,53].

5. CONCLUSION

Based on the results presented in the current study, process standardization in the operating room using digital support systems increased the efficiency of knee joint replacement procedures but had no significant influence on the quality parameter D62 acute haemorrhagic anaemia.

Specific to the treatment group, recovery room time was reduced by 20.20 minutes, changeover time by 4.14 minutes and hospital stay time by 1.93 days.

From a practitioner's perspective, these clinical practices and results can be generalized for average basic and standard care hospitals with many surgeons and high staff fluctuation.

In addition to other process standardization methods, such as instrumentation standardization, to increase efficiency and thus significantly reduce costs in orthopedics [54], the SPM offers an efficient digital solution to hospital management. Hospital management should consider implementing digital support systems to expand their options on efficiency optimization and further reduce their economic pressure.

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5.4 Article 4: Qualitative and Economic impact of standardized and digitalized Operation Room Processes in Obesity Surgery

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Abstract

Purpose:

The introduction of innovative digital solutions in healthcare lags compared to other industries but promise high potential to create value in efficiency and quality. Increasing economic pressure, force hospitals to optimize operating room (OR) processes, in which such solutions might provide additional support.

Materials and Methods:

This retrospective case-control and monocentric study investigated, if digitalized and standardized intraoperative surgical workflows of laparoscopic Roux-en-Y gastric bypass (LRYGB) have a significant impact on efficiency, quality, and economics. Logistic and linear regression models were used to apply propensity score matching (PSM) for efficiency and odds ratio for the quality analysis.

Results:

The study included 49 patients per group. The results demonstrate a significant increase in efficiency and cost-effectiveness in the treatment group. Length of stay (LoS) was 1.2 days less than in the control group (5.6 vs. 4.4). The mean of total OR- and skin-to-skin time increased by 3.7% (142.00 vs. 136.80) and 8.5% respectively (93.88 vs. 85.94). The standard deviation (SD) of total OR and skin-to-skin time decreased by 7.36 min. (26.86 vs. 34.22) and 8.98 min. (23.20 vs. 32.18) in the treatment group. The results of the odds ratio did not provide any conclusions on quality. Overall, costs were reduced by 318 € per patient and total revenue improved by 10,073 €.

Conclusion:

The implementation of digital workflow management systems in obesity surgery improves economic efficiency. Hospital management and payors should evaluate further support in research of the digitization of the OR, followed by reimbursement to increase and facilitate the accessibility to digital support systems.

Keywords:

Workflow management system, Digitization, Efficiency, Costs, Quality, Obesity surgery

Key Points:

- Digital surgical workflow management system increase efficiency in obesity surgery.
- No impact on quality between the control and treatment groups could be determined.
- Digital surgical workflow management systems have a positive impact on economics.
- Further prospective research on quality and efficiency parameters is needed.

1. Introduction

In 2021, healthcare expenditures in Germany accounted for 13.1% of total GDP. This is 1.2% more than in 2019 (before the COVID pandemic) [1]. The hospital sector is responsible for around one-third of the total spending on statutory health insurance [2]. The increase in prevalence of obesity has exacerbated the health economic impact of the disease, and its costs have grown disproportionately compared to all other healthcare expenditures [3,4]. European hospitals are confronted with increasing costs, competition, and a dual financing system, which provides insufficient investments and drives a need to control the costs per patient [5]. To manage this challenge, hospitals seek to optimize patient pathway efficiency while maintaining or improving quality. Efficiency is measured by assessing process time, quality, capacity, profitability, productivity, and liquidity [6]. Since the operating room (OR) accounts for approximately 40% of the total operational costs of hospitals [7], optimization of surgical workflow efficiency has become one of the main target areas [8,9].

To assess the efficiency of OR processes and improve quality management and processes, Neumuth et al. developed surgical process models (SPM) for quantification, data collection, analysis and visualization of surgical knowledge and individual techniques [10]. The SPM includes standardized steps of surgical procedures, which have been individually defined by surgical teams (OR-nurse, surgeon, and anesthetist) and afterwards digitalized. The steps are visually (monitor) and verbally available for the whole team and guide them through the surgical workflow. Each completed task must be confirmed by one of the team members. Differences in the expected process standards can be noticed and documented [11]. Previous research in ENT and Orthopedic has demonstrated a positive impact on efficiency and quality by reducing of skin-to-skin time, recovery room time, postoperative complications, and LoS [11–13].

Athanasiadis et al. reported a reduction of 6% of OR time in bariatric surgery by implementing a similar digital solution. By providing insights to the OR nurses on items needed and capturing real-time incidents causing delays, the ExplORer App contributed significantly to improve the surgical workflow [14].

No research has been published on the SPM in other surgical areas such as general and visceral, thoracic or neurosurgery. In addition, economic analysis has yet to be published to demonstrate digital support systems' economic impact on intraoperative surgical processes in specific digital workflow management systems [15].

Standardization has been proven to have a positive impact on efficiency and quality in bariatric surgery [16]. By introducing "Enhanced Recovery After Bariatric Surgery" (ERABS) protocols, Mannaerts et al. also showed that standardizing the entire process reduces procedural time and LoS. On the contrary,

complications increased, but the number of significant complications, readmissions or re-operations did not change [17]. The safety and improvement of LoS through ERABS with no difference in clinical outcome were further demonstrated by Fantola et al. The research group described shorter OR time by adding lean management methods (re-organization of the OR and logistic efficiency) to the ERABS protocol. This reduction is most likely related to LoS and complication rates [18].

The development of protocols and standardization of intraoperative surgical workflows and their continuous improvement through data collection, processing and analysis of surgical sequences offer further potential to improve hospital efficiency, quality, and profitability.

To summarize, the research conducted is supposed to fill the scientific gap of whether efficiency and quality will increase in obesity surgery by implementing digital workflow management systems to create economic value for hospitals and healthcare.

2. Materials and Methods

2.1 Research Framework

Standardizing surgical workflows and digitalization, such as the SPM, can generate value for patients and hospitals. There needs to be more evidence regarding the economic impact of digitalized OR workflows in surgery in the European healthcare market.

The research question “How does the application of digital workflow management systems affect cost efficiency in visceral surgery for laparoscopic RYGB procedures?” investigated whether digitalized and standardized surgical workflows in general and visceral surgery can generate value in efficiency, quality and cost-effectiveness.

This retrospective case-control trial attempts to answer the above research question with the evidence available.

Three Hypothesis were tested:

- Hypothesis 1: Digital workflow management systems in the OR generate positive outcome on OR time.
- Hypothesis 2: Digital workflow management systems in the OR generate positive outcome on process costs.
- Hypothesis 3: Digital workflow management systems in the OR generate positive outcome on process quality (intraoperative complications and post-OR complications up to 30 days)

2.2 Study Population

Four hundred eleven patients who underwent a laparoscopic Roux-en-Y gastric bypass as a primary surgical intervention at the St. Marien Hospital in Friesoythe from the 1st of January 2019 until the 31st of December 2021 were included in the study. One hundred seven patients underwent a procedure without the SPM, while the remaining 304 patients were assisted by the SPM.

2.3 Inclusion and Exclusion Criteria

Patients who were included in this retrospective study have been diagnosed with the ICD-Code E66.02: „Obesity from excess caloric intake Obesity Grade III (WHO) obesity in patients 18 years of age and older “and undergone a primary gastric bypass (Roux-en-Y), registered under:
Ø OPS: 5-445.41 (Other surgery on the stomach: gastroenterostomy without gastric resection (Bypass procedure): With stapled suture or transaction (Obesity): with gastrojejunostomy through Roux-Y-anastomosis: laparoscopic (based on data 2021)

Moreover, patient selection and indication for a bariatric procedure was performed in strict accordance of the S-3 Guideline under section 4.2.3 Indication of metabolic surgery of the S3-Guideline Surgery of Obesity and metabolic diseases (Version 2.3 – February 2018 – AWMF-Register Nr. 088-001).
All patients

- had a BMI of more than 40 kg/m2 at the time of surgery
- underwent pre-operatively an endocrinological exclusion diagnostic and a psychiatric assessment.
- had deficiencies of vitamin and trace elements balanced out pre-operatively.
- attended sessions of professional nutrition advice minimum of 6 months.

Patients without a psychiatric recommendation for a bariatric procedure were excluded and received no surgical procedure.

2.4 Methodological approach

This is a single centre, retrospective case-control study conducted solely at the St.-Marien-Hospital of Friesoythe in Germany.

All potential participants who fulfilled the inclusion criteria mentioned in the “Inclusion and Exclusion Criteria” section have signed written informed consent. They have been approached directly to explain the study purpose, data privacy policy, and potential benefits from data collection, analysis, and results.

The collected data has been pseudonymized and submitted to the German obesity registry of the „Deutsche Gesellschaft für Allgemeine- und Viszeralchirurgie“ named „StuDoQ“. There is a 30-day postoperative morbidity and mortality assessment. Intraoperative complications were detected, assessed, and submitted according to the guideline of the German obesity registry. For the specific case of intraoperative bleeding, the surgical team registered a complication, if a suture or clip had to be used. Patients’ follow-up, which included the assessment and submission of postoperative complications, was either performed by the surgical team in-hospital or at one cooperating diabetological practice 30 days after discharge. The complications have been categorized according to the official Clavien-Dindo classification.

As a result, a comprehensive dataset of the OR process was available as a base for statistical analysis.

The surgical team developed the SPM-based surgical pathway by standardizing their procedures into a digital workflow aiming at reducing unwanted deviations and improve quality. The digital workflow includes all procedure steps except for extraordinary events that are difficult to standardize. The created digital workflow, a standard operating procedure (SOP), of the RYGB was divided into 5 process phases (pre-surgery, access, surgery, closure, post-surgery). The process phases included 51 to 52 steps, depending on the closure of the Peterson-space during the process phase “Surgery”.

2.5 Biometry

Statistical analysis of the data obtained has been performed using SPSS Software, Version 29 Premium (IBM Corporation, Amonk, NY), Excel Statistics (XLSTAT) and R Studio, Version 2022.12.0+353.

From the raw dataset of 411 patients, 187 datasets were deleted because of missing information (variables or economic data). The final dataset contained 224 patients, 175 of them were found to be in the treatment group and 49 in the control group who had undergone a lap. RYGB. Table 1 shows the variables available for the analysis and the summary of statistics for the two groups of patients. The general variable “associated medical problems” was not used because specific individual-associated medical problems, such as hypertension or sleep apnea, were considered.

Table 1. Variables and summary statistics data in origin

	Min	Max	Treatment (SPM ==1)			Control (SPM ==0)		
Variable			Mean	Median	n**	Mean	Median	n**
AgeGroups	1	5		3			3	
○ Age 1 (≥29)					36			4
○ Age 2 (30-39)					46			10
○ Age 3 (40-49)					43			14
○ Age 4 (50-59)					36			11
○ Age 5 (≤60)					14			10
Gender	1	2		1			1	
○ Gender 1 (Female)					127			36
○ Gender 2 (Male)					48			13
Diabetes_mellitus_Typ2	0	1		0	26		0	17
Hypertension	0	1		1	98		1	28
Sleep apnea	0	2		0			0	
○ Sleep apnea1					29			9
○ Sleep apnea2					17			9
Dyslipidemia	0	1		0	20		0	7
Hyperureaemia	0	1		0	38		0	12
Polycystic_ovarian_syndrome	0	1		0	6		0	3
Joint_problems	0	1		1	127		1	36
Heartburn	0	1		0	70		0	19
Depression	0	1		0	55		0	12
Medical associated Problems*	0	8	2.5	3	---	2.9	3	---
Reflux_Symptom_Index	0	45	6.78	4	---	7.24	3	---
Medication	0	1		1	117		1	41
Heart_failure_NYHA	0	2		0			0	
○ NYHA1					44			14
○ NYHA2					12			1
Severe_COPD	0	1		0	35		0	13
ASA***_Score	1	4		3			2	
○ ASA_Score1					5			1
○ ASA_Score2					65			35
○ ASA_Score3					101			12
○ ASA_Score4					4			1
Smoker_Years_before_surgery_have they smoked	0	1		0	51		0	11
Previous_Operations	0	1		1	103		1	29
Close_mesenteric_gap	0	1		0	70		1	25
Mechanical_perioperative_thrombe	0	1		1	102		1	34
Perioperative_antibiotic_prophyl	0	1		0	84		0	21
Length_of_stay	3	22	4.6	4	---	5.6	5	---

*Count of medical associated problems (from Diabetes_mellitus_Typ2 to Depression)

**Considering that the disease is present

***ASA stands for Amercian Society of Anaesthesiologists

The analyses followed to verify the three hypotheses included logistic regression, linear regression and propensity score matching based on LoS.

LoS has been chosen because it likely correlates strongly with the efficiency parameter (OR time) and quality parameter (complications). A positive course of bariatric surgery and patient recovery, as described in research about ERABS, including shorter OR times and lower complication rates, reduces LoS [18]. Steps followed in the analysis [19] included the selection of covariates through regressions, selection of the model to create propensity scores (logistic regression), selection of the matching method (optimal matching), evaluation of the balance (standardized mean diff. and var. ratio), estimation of the effects of treatment in Length_of_stay (Mann-Whitney-Wilcoxon test), sensitivity (Rosenbaum) and power analysis (rank-biserial correlation for effect size estimation and pwr.t.test with a correction). The calliper selected for this analysis in optimal matching is 0.25 [20].

Variables in Table 1 are included in the formulas defined for regression analyses to select covariates and are the following:

glm(SPM ~ AgeGroups + Gender + Diabetes_mellitus_Typ2 + Hypertension + Sleepanea + Dyslipidemia + Hyperurecemia + Joint_problems + Heartburn + Depression + Reflux_Symptom_Index + Medication + Heart_failure_NYHA + Severe_COPD + ASA_Score + Smoker_Years_before_surgery_have_they_smoked + Previous_Operations + Close_mesenteric_gap + Mechanical_perioperative_thrombembolic_prophylaxis + Perioperative_antibiotic_prophylaxis

lm(Length_of_stay ~ SPM + AgeGroups + Gender + Diabetes_mellitus_Typ2 + Hypertension + Sleepanea + Dyslipidemia + Hyperurecemia + Joint_problems + Heartburn + Depression + Reflux_Symptom_Index + Medication + Heart_failure_NYHA + Severe_COPD + ASA_Score + Smoker_Years_before_surgery_have_they_smoked + Previous_Operations + Close_mesenteric_gap + Mechanical_perioperative_thrombembolic_prophylaxis + Perioperative_antibiotic_prophylaxis

Considering the binary scaling of the quality target parameters and the data were based on a case-control study, the odds ratios (OR) for intraoperative and postoperative complications were calculated.

2.6 Economic analysis

The subsequent economic analysis is calculated from the datasets of selected control and treatment group patients from the previously described PSM (LoS as defined output). The cost-benefit analysis includes LoS, if occurred, post-operative treatment until 30 days after discharge. The costs per minute in the OR have been calculated from internal hospital data sources for the years 2019, 2020 and 2021. It includes all relevant variable and fixed costs of the German DRG, such as staff costs of physicians and medical-functional technicians, material costs, and medical and non-medical infrastructure costs. In 2020 staff costs for nursing care in German Hospitals were officially outsourced from the DRGs and financed through a nursing budget. As the change occurred between data collection, the staff costs for nursing care have been excluded to ensure objective cost comparisons of both groups. To complete the cost-benefit analysis, the reimbursement for each patient was calculated based on the national DRG relative weight determined via coding multiplied by the prime rate of the state of lower Saxony.

3. Results

3.1 Statistical results

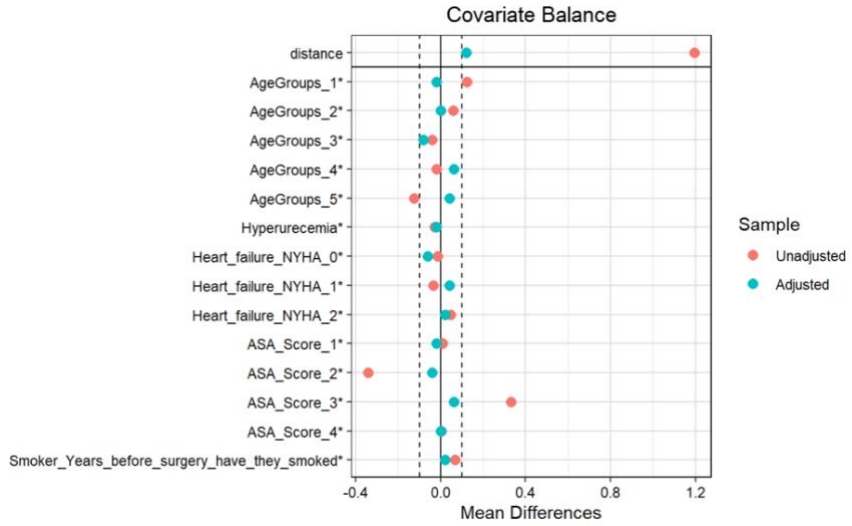
Two hundred twenty-four patients were included in the logistic regression model and used to identify the covariates that influence SPM use. This model identified “AgeGroups”, “Diabetes-mellitus-Typ2”, “ASA Score”, and “Close-mesenteric-gap” as covariates.

The applied linear regression model obtained the following covariates, which influence the output LoS: “SPM”, “AgeGroups”, “Hyperuricemia”, “Heart_failure_NYHA”, “ASA_Score”, and “Smoker_Years_before_surgery_have_they_smoked”.

The summary of both models showed that “AgeGroups” and “ASA Score” are the true confounders affecting treatment and outcome. The selection of covariates was conducted according to the criteria by Leite, who suggests including the true confounder plus the other covariates, which influence the output [21].

The matching and balance evaluation were performed according to Zhao et al. [22]. The process created 49 matched pairs, and the two groups resulted with similar means for age, ASA Score, hyperuricemia, heart failure NYHA and smoker status before surgery. The standardized mean difference and the variance ratio showed that the matched covariances are balanced [22,23]. Figure 1 shows the balance before and after adjusting.

Fig. 1. Covariate Balance before and after adjusting.



LoS is different between the treatment and the control group (two sided Mann-Whitney-Wilcoxon test: W=2078, p-value <0.001, 95% CI= [1.00, 2.00], difference in location=1.00).

The power analysis resulted in 0.947 and indicated that the minimum size for each group needs to be at 31 patients (d = 0.73, sig. level = 0.05, power = 0.8). Table 2 presents the regression analysis results conducted before and after matching, with Length_of_stay as dependent variable. The results indicate that after matching, the impact of predictor variables Heart_failure and ASA_Score is higher than before matching, when all patients are considered. It also shows that the model fits better after matching, as the values of R2 and R2 adjusted are higher than in the matching model before (26%-22% before matching, 52%-45% after matching).

Table 2. Results for regression before and after matching, output Length_of_stay (LoS)

Covariates	DV: Length_of_stay (linear regression)							
	Before matching (n=224)				After matching (n=98)			
	B	SE	IC (2.5%)	IC (97.5 %)	*B*	SE	IC (2.5%)	IC (97.5%)
Intercept	5.31***	0.89	3.56	7.07	5.67**	2.0	1.69	9.64
SPM	-1.18***	0.33	-1.83	-0.53	-1.22***	0.35	-1.91	-0.54
AgeGroups2	0.04	0.39	-0.74	0.81	0.67	0.79	-0.89	2.23
AgeGroups3	0.56	0.39	-0.22	1.33	0.57	0.73	-0.89	2.03
AgeGroups4	0.42	0.42	-0.41	1.24	0.76	0.73	-0.70	2.22
AgeGroups5	-0.53	0.52	-1.56	0.50	-0.21	0.80	-1.79	1.37
Hyperurecemia	-0.70*	0.32	-1.32	-0.08	-0.58	0.43	-1.43	0.27
Heart_failure_NYHA1	0.58(.)	0.33	-0.06	1.22	0.37	0.39	-0.41	1.16
Heart_failure_NYHA2	1.92***	0.57	0.79	3.04	3.35**	1.12	1.11	5.59
ASA_Score2	0.10	0.81	-1.50	1.69	-0.48	1.83	-4.11	3.15
ASA_Score3	0.40	0.80	-1.17	1.97	-0.36	1.85	-4.03	3.31
ASA_Score4	5.11***	1.19	2.76	7.46	7.37**	2.27	2.86	11.9
Smoker_Years_before_surgery_have_they_smoked	-0.80**	0.29	-1.37	-0.22	-1.13*	0.47	-2.07	-0.19
RSE	1.87 (df 211)				1.68 (df 85)			
R2	0.26				0.52			
Adjusted R2	0.22				0.45			
F-statistic	6.32 (df 12 and 211)				7.67 (df 12 and 85)			
F-statistic p-value	0.000002				0.000002			

Sig.: <0.001***, <0.01**, <0.05*, 0.1(.)

After PSM was completed, the patient data of both groups revealed that the mean of LoS was 1.2 days more in the control group (5.59) than in the treatment group (4.43 days). The statistical result shows that SPM significantly impacts the LoS of patients undergoing a RYGB.

The mean of total OR time in the control group was 5.20 min lower, but the SD was 7.36 min higher than in the treatment group. The clinical or economic relevance must be questioned since the results are far below the 10% difference.

The mean of the skin-to-skin time after PSM was 7.94 min and for the patient preparation 0.26 min higher in the treatment group. Like total OR time, the SD of skin-to-skin time decreased in the treatment group resulting in 8.98 min less, while it shifted for the preparation time being 3.50 min higher than the control group. A detailed overview of the parameters can be found in Table 3.

Table 3. Results of measured efficiency parameters in the control (No-SPM) and treatment (SPM) group.

Parameter	No-SPM	SPM	Difference (with SPM implementation)
LoS (Mean)	5.59 days	4.43 days	- 1.16 days
Total OR-Time (Mean)	136.80 min.	142.00 min.	+ 5.20 min.
Total OR-Time (SD)	34.22 min.	26.86 min.	- 7.36 min.
Skin-to-skin time (Mean)	85.94 min.	93.88 min.	+ 7.94 min.
Skin-to-skin time (SD)	32.18 min.	23.20 min.	- 8.98 min.
Patient preparation time (Mean)	34.63 min.	34.89 min.	+ 0.26 min.
Patient preparation time (SD)	11.01 min.	14.51 min.	+3.50 min.

The odds ratio examined whether the treatment and control subsamples differed in the intra- and postoperative quality parameters. Tables 4 and 5 show the cross table of frequencies for the registered complications.

Table 4. Cross table of diagnosis of intraoperative complications in the control group (no-SPM) and treatment group (SPM).

Quality Targets	No-SPM	SPM	Total
Complications Intra-OP (No)	41	33	74
% within Intra-OP complications	55.4%	44.6%	100.0%
Complications Intra-OP (Yes)	8	16	24
% within Intra-OP complications	33.3%	67.7%	100%
Count intra-OP complications (No&Yes)	49	49	98

Table 5. Cross table of postoperative complications in the control group (no-SPM) and treatment group (SPM).

Quality Targets	No-SPM	SPM	Total
Post-operative complications: No	46	44	90
% within post-OP complications	51.1%	48.9%	100.0%
Post-operative complications: Yes	3	5	8
% within post-OP complications	37.5%	62.5%	100.0%
Post-operative complications: (No & Yes)	49	49	98

Two out of 16 intraoperative complications occurred in the SPM group, leading to grade 1 postoperative complications and readmission without additional surgery. Within the non-SPM group,

one of the 8 intraoperative complications led to a grade 3 postoperative complication without readmission.

The mean LoS of patients with intraoperative complications were 4.1 days in the SPM-supported group and 6 days in the non-SPM group.

The odds ratio of intraoperative complications in the two groups were calculated and found to be 1.74 (CI 0.39 – 7.73). Calculating the odds ratio of postoperative complications resulted at 2.48 (CI 0.95 – 6.52).

More research needs to be conducted to draw further conclusions about the impact on outcomes when using SPM.

3.2 Economic results

The economic impact analysis is focused on the efficiency parameter of LoS.

Based on the hospitals provided dataset related to the INEK cost framework [24], the costs per patient per day in the regular ward have been calculated at 376.23 € in the control group and 371.01€ in the treatment group. The costs differ because mainly staff and material costs changed during 2019 to 2021. To calculate cost savings per patient concerning LoS, the costs of the control group were used before the SPM was implemented. The cost details at the regular ward are displayed in Table 6.

Personnel costs depend on LoS and are allocated according to the INEK calculation. The costs increase due to the higher cost rate per day, driven by lower case numbers because of Covid (despite decreasing dwell time with SPM). Slight deviations in the results of the following calculations are due to rounding differences in Excel and the calculated decimal places.

Table 6. Costs of RYGB per treatment day on normal ward (own illustration based on Lahmann (2021).

Cost type		Time frame				
		2019 No SPM	2019 SPM	2020 SPM	2021 SPM	Average SPM
1	Staff costs of physicians	96.64 €	106.26 €	148.96 €	152.14 €	148.88 €
2	Staff costs of nursing care	131.37 €	48.73 €	77.47 €	60.43 €	62.15 €
3	Staff costs of medical-technical functions	3.22 €	3.54 €	4.39 €	4.19 €	4.18 €
4a	Pharmaceutical material costs	3.09 €	1.14 €	4.58 €	4.36 €	4.20 €
4b	Pharmaceutical material costs	- €	- €	- €	0.63 €	0.50 €
6a	Material costs other medical material	35.01 €	12.98 €	64.27 €	10.49 €	18.33 €
6c	Material costs other medical material	- €	- €	2.53 €	- €	0.36 €
7	Staff and material costs medical infrastructure	17.13 €	18.84 €	22.63 €	23.13 €	22.79 €
8	Staff and material costs non-medical infrastructure	89.78 €	98.72 €	114.75 €	110.71 €	110.55 €
Total RYGB costs per treatment day on normal ward		376.23 €	290.22 €	437.05 €	365.46 €	371.08 €

As results have shown, the LoS is reduced by 1.2 days. The LoS reduction of 1-day results in cost savings of 376.23 € per patient (21% reduction of LoS with SPM). A similar reduction of LoS on the annual workload (289 bariatric procedures in 2019) could drive cost savings of 106,129 € per year.

Alternatively, reducing the length of stay by 21% (4.43 days versus 5.59 days) could result in 336 additional days of available beds, allowing for approximately 76 more surgeries per year under the assumption that there were no constrains in theatre utilization.

In principle, some costs are assigned directly to the case, such as material costs. All other costs are allocated to the case using cost keys, such as LoS or skin-to-skin time. All costs that could not be directly associated with a specific patient were calculated to calculate the costs per OR-minute. An OR average cost was 21.39 € per OR-minute and a skin-to-skin minute was 34.04 € before the SPM was implemented (Table 7). Sixty-nine percent of costs resulted from costs of medical staff.

Table 7. Average cost per minute (skin-to-skin)

		Average costs per minute (skin-to-skin)				
Cost type		**2019 no-SPM**	**2019 SPM**	**2020 SPM**	**2021 SPM**	**Average SPM**
1	**Staff costs of physicians**	1071.84 €	1156.20 €	1222.00 €	951.23 €	1004.99 €
3	**Staff costs of medical & technical functions**	934.88 €	846.64 €	1073.70 €	1346.15 €	1284.84 €
4a	**Overhead Pharmaceutical material costs**	42.18 €	52.74 €	29.53 €	68.18 €	61.73 €
6a	**Overhead Material costs other medical material**	496.90 €	616.50 €	876.06 €	182.81 €	311.83 €
7	**Staff and material costs medical infrastructure**	114.65 €	142.78 €	146.72 €	145.97 €	146.52 €
8	**Staff and material costs non-medical infrastructure**	265.28 €	329.09 €	382.97 €	314.64 €	327.18 €
Total indirect costs per surgery		2925.74 €	3143.95 €	3730.97 €	3008.97 €	3137.10 €
Mean skin-to-skin time in minutes		85.94 €	115.00 €	92.14 €	92.56 €	93.88 €
Costs per OR minute (skin-to-skin)		34.04 €	27.34 €	40.49 €	32.51 €	33.42 €
Mean total OR time in minutes		136.80 €	181.67 €	139.86 €	139.33 €	142.00 €
Costs per OR minute (total OR time)		21.39 €	17.31 €	26.68 €	21.60 €	22.09 €

Average costs varied from 2019 to 2021. It stayed the same after the implementation of SPM (+3.2% costs per minute of OR time and -1.8% costs per minute of skin-to-skin time).

The average total procedure cost was 7566 € in the control group and 318 € lower (7249 €) in the treatment group. This is a decrease of 4,2% in costs after the implementation of the SPM.

While the average revenue from the DRG was 7148 € in the control group and 7036 € in the treatment group, respectively, total income was negative in both groups. In the control group, the hospital had a negative income of -20,472 €. The reduction of LoS in the SPM group led to a significant decrease of almost 26K € of average ward costs. The increase in OR time resulted in cost increase of around 5500 € (OR and Anesthesia), which is about 113 € more per case in the treatment group. Overall, the negative result was reduced by almost 50% (49,2%) to -10,399 € reducing the loss incurred by the hospital. Extrapolating these results to 289 cases would lead to a negative income of -120,742 € in the control group and -61,332 € in the treatment group. Extra costs and revenues from postoperative

complications could not be considered due to a lack of available data. The comprehensive cost-benefit analysis is displayed in Table 8.

Table 8. Total cost-benefit overview. Bold values show the difference of total costs and income, which result in revenues per procedure and total revenues without and with SPM.

Cost Center Group	**No SPM**	**SPM**
01 - Normal ward	102,268.17 €	76,274.97 €
02 - Intensive care unit	- €	
04 - Operating room	188,541.98 €	193,234.03 €
05 – Anesthesia	51,393.21 €	52,237.51 €
08 - Endoscopic room	- €	1069.88 €
09 – Radiology	3452.11 €	5890.44 €
10 – Laboratories	3491.79 €	5643.52 €
11 - Diagnostic areas	1272.78 €	2450.97 €
12 - Therapeutic procedures	20,079.75 €	18,224.68 €
13 - Patient admission	247.72 €	157.90 €
Total	**370,747.51 €**	**355,183.90 €**
Average costs of RYGB (2019)	7566.28 €	7248.65 €
Income	**350,275.63 €**	**344,785.02 €**
Average income of RYGB (2019)	7148.48 €	7036.43 €
Average Revenues per procedure	**- 417.79 €**	**- 212.22 €**
Total revenues (49 cases)	**- 20,471.88 €**	**- 10,398.88 €**
Revenues extrapolated to total procedures in 2019 (289 cases)	- 120,742.31 €	- 61,332.17 €
Cost savings due to LoS per case	376.23 €	
Revenues by reduced LoS (2019)	- 41.56 €	
Additional costs by longer skin-to-skin time	- 272.32 €	
Total revenues (289 cases)	- 90,711.33 €	

Concluding the three hypotheses can be answered in the following below:

- Hypothesis 1: Digital workflow-management-systems in the OR generate positive outcomes on OR time concerning SD but not in total mean time.
- Hypothesis 2: Digital workflow management systems in the OR generate positive outcomes on process costs, because the reduction of LoS and SD positive prevails the prolonged OR time.
- Hypothesis 3: Digital workflow management systems in the OR do not generate positive outcome on process quality (intraoperative complications and post-OR complications up to 30 days). Since the 95% CI were very wide, further research to draw conclusions is needed.

4. Discussion and Limitation

The results have demonstrated that implementing a digital workflow management system reduces LoS, SD of total OR time and skin-to-skin time driving an increase in efficiency. On the contrary, in the SPM group, OR- or skin-to-skin time increased, which might be caused by the learning curve of the SPM.

While previous studies in orthopedics and ENT have shown an improvement in time, surgical procedures that are already highly standardized and performed in high-volume centers, such as lap. RYGB in Friesoythe, which offers different efficiency gains at first glance. Factors such as fluctuations in medical staff between 2019 and 2021, or the COVID pandemic influencing processes and workflows might have impacted OR time and skin-to-skin time. Similar aspects account for the analysis of patient outcomes.

Using SPM could not be associated with complications from the odds ratio analysis. One patient in the control group with minor complications (Grade 2) and three patients from the treatment group with minor or major complications (2 times grade 1 and 1 time grade 3b) had to be re-admitted because of postoperative complications, which led to additional costs. Research demonstrated that previous general surgeries could be related to complications. Since the treatment group includes more patients who had general surgery before, it could explain the difference in complications (59,2% vs. 73,5%).

The hospital registry shows that postoperative complication rates of lap. RYGB decreased from 13.3% to 9.8% from 2019 to 2022. In a stable environment without the COVID pandemic, the results on efficiency and quality might have been different, which should be investigated in further research.

As the hospital has generated negative revenues in the control group, the additional capacity in the regular ward could allow the additional treatment of 76 procedures. Every additional procedure in an environment with similar costs for medical staff and same DRG revenues of 2019, could generate revenues of 1589 € (Indirect minus all other costs). The hospital would have had to perform an additional 76 procedures to reach the break-even point, as illustrated in Table 9. Due to the efficiency gain and no significant decrease in quality, this break-even point shifted after the installation of SPM towards 30 additional procedures required to break even.

Table 9. Break-Even Calculation without and with SPM

	No-SPM	**SPM**
Cost per OR-Minute (incision-to-suture)	34.04 €	33.33 €
Indirect costs per procedure	2925.74 €	3129.04 €
All other costs per procedure	4640.53 €	4119.61 €
Costs per additional OR-minute without staff (incision-to-suture)	10.69 €	8.95 €
Additional costs per procedure (indirect costs)	919.02 €	840.34 €
Potential revenues of every additional procedure	1588.93 €	2076.48 €
Additional procedures needed to reach break-even-point	75.99	29.54
Potential profit by additional 76 procedures (no extra med. staff costs)	120,758.68 €	Not calculated
Total revenue (no extra med. Staff costs and 365 procedures	16.37 €	Not calculated

With those calculations and results, hospital management should investigate whether other unprofitable procedures can be outsourced to increase the profitability of obesity surgery. Also, decreasing SD in OR time and skin-to-skin time could improve the planning of cases and changeover time. This positive effect on efficiency could not be investigated due to missing available data but should be researched in further trials.

Overall costs of the SPM must be considered for a complete cost-benefit analysis. Considering the approximate list price of 100,000 €, the amortization due to the decrease in costs of approx. 59,000 € per year (-121,000 € revenues vs -61,000 € revenues) would be reached after around 1 year and 8.3 months. Data of additional positive financial impact of depreciation was unavailable to include in this analysis.

This study has some limitations, including the retrospective design in a single center, the sample size in the control group, and a healthcare setting severely affected by the COVID pandemic and changes in nurses' remuneration. The lack of entire data sets of 187 patients created a significant limitation for the sample size. More considerable control and treatment groups would have increased the validity of results and might led to further conclusions about patient outcomes. Another limitation was that the provided data set did not allow an analysis of changeover and recovery room time. As previous research demonstrated a positive impact on recovery room time, a comparison would have provided new scientific evidence. In addition, other digital support systems for workflow management, recognition and prediction exist that have shown through machine learning how to automatically provide workflow analysis and accurate recognition of surgical phases and steps [25–27]. These systems could provide additional data to continuously adapt and evaluate standardized surgical workflows to improve efficiency, quality, and profitability. This should be included in further research.

In addition, an economic analysis with standardized cost data and in multi-center study should be performed to make further concrete statements.

However, this is the first research demonstrating the economic impact of a digital workflow management system through improved efficiency. In addition, it is the first study investigating the effects of SPM in general & visceral surgery.

5. Conclusion

This retrospective case-control trial has shown that implementing a digital workflow management system significantly improves the efficiency of the lap. RYGB and leads to a positive economic impact. Hospital management and payors in European countries should consider the implementation and financial support of the introduction of digital support systems (DSS), as it can improve the overall economic burden. The combination of implemented solutions of ERABS and DSS promises even further potential to improve efficiency and quality to cope with the recent challenges in healthcare. Further prospective research on digital workflow management systems, such as the SPM, workflow recognition, as well as prediction systems in obesity surgery and other complex surgical procedures, should be done to reveal its full potential and to inaugurate new reimbursement opportunities.

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6 Discussion

The Thesis had identified a significant research gap, which served as the foundation of the developed hypothesis. No research had been carried out before to investigate whether DSS has an economic impact on advanced surgical procedures, specifically in G&V surgery. To derive a conclusion, the articles addressed the primary and several underlying research questions, which can be summarized as follows:

How do standardization and digitization of intraoperative surgical workflows impact quality, efficiency and economics?

The SLR has shown that standardization of surgical procedures significantly improves efficiency and reduces costs while maintaining quality. More evidence with complex and costly systems must be generated to draw correlations and understand their full economic potential. Research about a combined approach of standardization and integrated DSS positively impacted efficiency and quality. The amount of research in this area was low. Only five studies reported an outcome on intraoperative surgical workflows. None of them provided any economic analysis.

Based on those findings, two retrospective case-control trials by implementing SPM were undertaken at the St-Marien-Hospital in Friesoythe to address the following research questions:

How do standardization and digitization of intraoperative surgical workflows in advanced procedures affect efficiency?

The results for knee-joint replacement and RYGB procedures demonstrated increased efficiency (reduction of Length of Stay and SD of skin-to-skin time). The study of knee joint replacements also led to a reduction in changeover time and recovery-room time. Due to missing data or data which could not assigned to specific RYGB procedures, those parameters could not be assessed.

How do standardization and digitization of intraoperative surgical workflows in complex procedures affect quality?

No significant effect on quality ratios could be shown based on the results of the odds ratio analysis. Demonstrated improvements in quality (complication rates) and efficiency (OR time) of standardized and digitized RYGB procedures indicated by Aird et al. (2017) and Athanasiadis (2021) were not found with the implementation of SPM in Friesoythe. The reasons for that can be manifold. The previous level of standardized surgical workflows was not described and could have been different. Also, detailed patient characteristics and level of medical-associated problems have not been presented in previous research. As literature has already demonstrated, this can significantly impact outcomes and efficiency. Another factor which plays an important role but was not described in the studies is the fluctuation of medical staff. Learning curves and expertise play a significant role in efficient intraoperative surgical workflows. In addition to these potential factors, it needs to be considered that

previous research was not conducted during COVID-19, which might have also impacted the research results in Friesoythe.

How do standardization and digitization of intraoperative surgical workflows impact the hospital's economics?

The economic analysis of RYGB procedures with or without SPM indicated that digital workflow-management systems have a positive impact and decrease hospitals' financial constraints. The hospital achieved total cost savings of 10,073€, or 318€ per patient. Given the recent accomplishments of DSS for workflow recognition and prediction, additional evidence for improved clinical and administrative decision-making and education purposes could be provided. This includes enhanced opportunities to increase efficiency and improve quality by continuously adapting standardized and digitized surgical workflows. Even though technical challenges exist due to surgical variability, the continuing trend towards standardizing complex surgical procedures might accelerate systems' adaptability and transferability. These upcoming digital solutions might also positively impact the economic performance of the peri- and intraoperative workflow.

The conducted research had several limitations. The sample sizes were small, even though the power analysis of the RYGB trial stated that 31 patients per group were sufficient. Concerning the sample size, the lack of fully available data sets per patient significantly reduced the amount. Larger groups might have provided further evidence, especially regarding quality and efficiency parameters, such as recovery-room time and changeover time. In addition, the retrospective single-centre design only generated results from one hospital with specific infrastructure and requirements. Several centres with different conditions (public/private or primary/focal care provider, etc.) and European cost structures could have provided more relevant evidence. Another limitation was the implementation and assessment of only one specific digital workflow-management-system. Even though it was tight to the limited hospital budget, two or more different digital systems might have helped to draw correlations and comparisons and delivered additional results on quality, efficiency, and economics.

7 Conclusion

The healthcare market still lags in digital development compared to other industries. Because of the high dynamic, key stakeholders such as medical device companies must constantly adapt their Go-to-market models and increasingly invest in digitization. As indicated in this thesis, healthcare providers, such as hospitals and their medical staff, are under even higher economic pressure to adjust their processes and workflows. Previous research demonstrated that standardization of intraoperative surgical workflows in various areas improves efficiency while quality remains the same or even improves. Economic benefits could be realized, and the burden of cost management in the OR decreased. By adding digital workflow management systems, initial positive impacts on efficiency in ENT, G&V and Orthopedics were indicated but lacked its contribution to quality and direct and indirect costs. Further research on more advanced and costly procedures was needed to draw correlations and confirm its additional economic impact.

The research carried-out in this thesis demonstrated increased efficiency for patient groups supported by the digital workflow-management system, SPM, in knee-endoprosthesis and RYGB procedures. The odds ratio analysis did not allow any conclusions to be drawn on the impact on quality.

For the first time, the associated complete economic analysis demonstrated that digital workflow management systems significantly contribute to cost reductions. This was shown by implementing SPM for intraoperative workflows in obesity surgery. These findings will provide new evidence for hospital management to assess the value of investments in digital solutions for efficiency and economic outcome purposes. It will also offer valuable financial data to payors, which could positively influence and accelerate the MIS integration and its reimbursement within the hospital's landscape. This thesis's research can further serve as the basis for future research in digitization of perioperative workflows (prediction and recognition).

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9 Appendix

Marketing-Control in Unternehmen der Medizintechnik

Marketing control in medical technology companies (English Translation)

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Summary

Medical technology companies are facing new and, above all, significant challenges due to regulatory and legal changes and increasing digitization. To meet these requirements, the function of marketing controlling is becoming more and more critical. However, companies are only making insufficient investments urgently needed to ensure future viability.

First, a secondary analysis of the status quo of marketing controlling in the German healthcare market is carried out. Based on this, it is shown how medical technology companies can use selected marketing controlling instruments to add value. Against the background of remaining competitive in the future, the influence of digitization and big data is presented.

1. Introduction

With around 7.5 million people in employment, the healthcare industry is one of Germany's most important economic sectors—just under 17% of the 44.5 million people in the employment workforce in the healthcare sector. The number of jobs has been rising continuously for the last ten years, and with 1.2 million new jobs created since 2010, the industry is currently one of the leading growth drivers in Germany. 372 billion euros p.a. are generated here, corresponding to around 12.1 per cent of the total gross domestic product (G.D.P.). In terms of gross value added, every eighth euro is generated in the healthcare industry. The growth in gross value added in the healthcare sector is 4.1 % p.a. and is, therefore, 0.8 % higher than the current average growth of the economy because the healthcare industry a large proportion of its inputs from other sectors of the economy, such as the manufacturing industry (around 25%), it significantly strengthens Germany as a business location (see BMWi 2020, p. 6 f.; BVMed 2020, p. 3 f.).

The healthcare industry in Germany can be divided into four areas: "medical care", "industrial care", "industrial healthcare", and "other sub-sectors". Medical care generates almost 200 billion euros, more than half of the total value added (see BMWi 2020, p. 7). Alongside medicinal products for human use, medical technology products are among the core areas in the industrial healthcare industry. These two core areas secure 490,000 jobs in Germany (cf. BMWi 2020) and generate 81.2 billion euros. The

industrial healthcare sector thus generates 21.8% of the gross value added of the entire healthcare industry.

The medical technology and products sector employs around 200,000 people in Germany. The total turnover of manufacturing companies with over 20 employees in 2019 amounted to 32.4 billion euros. This is an increase of 10.4% compared to the previous year. The domestic turnover of these companies amounted to 11.5 billion, which means a growth of 9.5%, which was slightly lower than the growth in foreign sales (see BVMed 2020, p. 5). Even though EBIT margins in the medical technology sector are above average, the industry faces several challenges.

The legal and regulatory framework conditions for market launch and monitoring have been regulated for over 25 years by the Medical Device Directive (M.D.D.) and the Medical Devices Act (MPG). The introduction of a new European regulation planned for 2021, The second pillar is dual financing system (Private vs. public) , concerns all investment. The public investment budget is the responsibility of the individual federal states. For investments such as maintenance, modernization, or technical equipment, around six billion euros per year are required in Germany. Currently, however, the Medical Device Directive (M.D.D.) and the Medical Devices Act (MPG), as well as Medical Device Regulation (M.D.R.), foresee some changes will come into force.

For example, these will lead to new classifications and assessment procedures for product groups. Other changes include increased requirements for clinical evaluations, the creation of clinical data, and risk and quality management systems. Furthermore, there will be new regulations for monitoring medical devices after their market launch (see Dispan 2020, p. 36). These and other changes to the M.D.R. aim to improve the quality of medical devices and ultimately increase patient safety. Furthermore, it is a declared aim to enhance the medical evidence in clinical studies and the traceability of medical traceability of medical devices (see Dispan 2020, p. 36).

On the other hand, manufacturers are criticizing the new regulation. According to a survey of 320 manufacturers, 79% of the companies surveyed believe the conditions will be much more challenging to launch innovative products on the market. Just under four companies expect market access costs to rise, and around half of the manufacturers anticipate streamlining their product lines (see D.I.H.K. 2019, p. 7). As a result, the pressure from the new M.D.R. will increase, mainly for small and medium-sized companies. Around 30% of medical devices are expected to disappear from the market, resulting in supply bottlenecks. Could arise (see BVMed 2020, p. 12).

In addition to the new legal and regulatory framework conditions in medical technology, the public financing and investment opportunities for service providers (e.g. municipal hospitals) have (e.g. municipal hospitals) have declined significantly. In Germany, there is a dual financing system to cover care services. Statutory in this model, the statutory and private health insurance funds bear the operating costs of the service providers. These include, for example, costs for medical services or

specialist staff required (doctors, nurses, assistants, etc.) (see Ärzteblatt 2019). D.R.G.s (Diagnosis-Related Groups), which summarize patient cases with similar costs, the hospital services are documented and billed.

Several changes have been introduced during the hospital structure reform in recent years. Among other things, the quality of hospital care and the volume control in inpatient care were realigned, and the inpatient care was to be realigned. The calculation of the remuneration systems in hospital systems is more representative thanks to an improved basis (cf. B.M.G. 2017). In addition, a change was made to the calculation method, resulting in reduced remuneration for material cost-intensive services. This led to a new price structure for service providers, such as hospitals specializing in specific disciplines. This means a price pressure situation for service providers, such as hospitals specializing in particular disciplines, and the interest groups involved, such as manufacturers.

The second pillar of the dual financing system concerns all investments. These investment budgets are the responsibility of the individual federal states. For investments such as maintenance, modernization, or technical equipment, around six billion euros per year are required in Germany. However, only about half of the necessary investment funds have been available (see Ärzteblatt2019). Due to the shortage of investment funds, service providers are increasingly looking for ways to reduce running costs. For example, large purchasing groups (E.C.G.) to minimize material costs.

Similarly, the continuous optimization of work processes along the patient pathway within a hospital also leads to more efficient and usually more cost-effective processes. For medical technology companies, these measures on the part of service providers, alongside other changes, lead to increased price and competitive pressure. Digitalization in the healthcare sector offers new solutions to counter the changing market conditions. Measured by the economic index, the healthcare sector has 36 out of 100 points, and it is one of the areas that is still very under digitalized (average is 49 points) (see BMWi2020, S. 34).

2 Marketing control in medical technology companies

2.1 Overview

Marketing is applicable in the healthcare sector in all areas of the appropriate care process. Such a process can be divided into prevention, diagnosis & therapy, and aftercare (see Meffert and Wölde-Lübke 2017, p. 214). For each, primary interest groups focus on specific customers or business partners and concentrate on certain customers or business partners. As shown in the market description, specific government regulations determine the framework of the supply process. For example, the provision of care and remuneration for individual forms of therapy (D.R.G.) are heavily regulated. These regulations are necessary because, for example, information on the need for and benefits of care is inadequate or distorted. This is clearly illustrated by the example of a patient's evaluation of medical services. Patients often overestimate or underestimate the medical services provided during

their stay in the hospital due to a lack of medical understanding or incomplete provision of information by the service provider during treatment. In addition, data on patient satisfaction and the quality of care are only partially collected, evaluated, and shared with others and other stakeholders along the care process.

With their marketing activities, medical technology or pharmaceutical companies can find themselves in each of the three pillars mentioned above. Medical technology companies that manufacture and offer products and offer products or services for surgical procedures, for example, focus their marketing activities mainly on the area of diagnosis & therapy.

Their target groups are defined by the stakeholders and decision-makers within the healthcare process. In this case, their primary target group is the Doctors directly involved. Due to the constantly changing market conditions, with an increased focus on the quality of care and economic efficiency, other target groups such as purchasers or managing directors have come into focus; these must also be considered.

In this context, applying the marketing mix of the four Ps for medical technology manufacturers is only recommended to a limited extent. A new approach, such as SAVE, considers the changed requirements and market conditions. With around 400,000 medical products from various manufacturers in the German market for diagnostics, implants, surgical instruments and surgical material, customers must recognize technological advantages, clearly remember technical advantages or differentiate between functions, primarily because the product life cycle is becoming ever shorter. Due to the products and services on offer, compelling needs on the part of the players are recognized by the players involved in this supply process. Still, they can rarely be brought in but are seldom linked to manufacturers and products.

However, this challenge can be overcome by providing targeted offers for customer needs. In contrast to other industries, a medical technology company must meet specific requirements before the product can be launched on the market and advertised with benefits. It can be promoted. These requirements include risk analysis and assessment to demonstrate safety, the performance of a clinical evaluation and testing to prove performance and efficacy, and a comprehensive quality management system. (see BVMed 2020, p. 17). It is not without reason that many direct users are already involved during product development. "Access" refers to the optimal availability of products and information across all channels. In contrast to product availability in other industries, medical products are only partially available online. Many products, such as surgical materials or simple medical instruments, can be obtained from dealers or manufacturers.

More complex products are still primarily sold via traditional sales channels, such as a sales force. Nevertheless, medical technology companies need to market their products and the required

information via various channels, online, customer support (telephone or digital), social media, or the sales team.

In the current environment, with many competitors and economic challenges for hospitals and private hospital companies, the positioning of a product is determined based on production costs or competitive prices, which are less and less likely to lead to medium to long-term success. Instead, a clear communication strategy should be used to demonstrate the product's added value for the customer. This can take various forms, such as increased patient safety or more efficient and effective treatment with effective work processes for medical staff.

As the final measure of the SAVE marketing model, medical technology companies convince their customers via inbound marketing. In contrast to advertising or public relations work, which does not directly involve the customer, greater emphasis is placed on information and advice. With such so-called education, building a partnership-based customer relationship during and after the purchasing process is essential. This inspires trust in the process on the part of the customer and offers the company the opportunity to continue to tailor products to individual customer needs.

Control in the healthcare sector is primarily concerned with effectiveness and efficiency when providing mainly from effectiveness and efficiency. In addition to products, services play a decisive role in the healthcare sector, meaning several unique service control features must be considered. Examples of relevant factors that need to be considered include the following:

- Inclusion of external variables: The service's production always involves the service's recipient; in this case, the patient is always involved. This can lead to planning uncertainties or standardization problems.
- Hard and soft key figures: In addition to hard vital statistics, such as bed utilization, times in the operating theatre or the number of procedures, soft crucial statistics such as patient or user satisfaction such as patient or user satisfaction, trust, or quality of life, play an important role play an important role. Soft indicators are generally difficult to measure.
- Advanced performance of service providers: Hospitals must maintain capacity such as staff, rooms, and equipment. Suppose the number of patients is insufficient for 100 per cent capacity utilization and cost coverage. In that case, there is a risk of price competition competition, which can lead to insolvency (see Tiemann and Matusiewicz 2017, p. 274 f.).

In addition to these factors, there are several other specific circumstances in the planning, control, and reporting of the controller in the healthcare sector. Due to their minor relevance to the following topics in medical technology in medical technology, these will not be discussed in detail.

2.2 Selected instruments

Marketing control covers a wide range of tasks within the company. To subsequently focus on individual aspects and instruments of marketing control in medical technology, an empirical study by

the University of St. Gallen study by the University of St. Gallen (see Reinecke 2016). A standardized online questionnaire with a Likert scale from 1 (strongly disagree) to 7 (strongly agree) was used for the empirical study. The study was conducted in German-speaking countries, mainly in Switzerland. Out of 4226 contact managers, 388 answered the questionnaire. Almost 2/3 of the respondents (64 %) were in a managerial position in the company, as managing directors, supervisory board, or board of directors. The remaining respondents consisted of marketing or sales managers and controllers. 34 % of the participating companies had more than 500 employees, 27% had between 50 and 499 employees, and 39% had fewer than 50 employees (see Reinecke 2016, p. 202).

One study finding is that almost no company was satisfied with its marketing control. With a satisfaction score for company management of 3.57, this can be described as moderate. Overall, it was stated that the most significant challenges for marketing control are, on the one hand, the "measurability of measurability of marketing" and the development of an "information and data basis in marketing". However, Reinecke (2016, p. 205) noted in the analysis that it is precisely these challenges can be positively influenced by marketing management itself. Concrete objectives with operationalizable key figures are suitable for improving the measurability of marketing. Investments in market research can solve the second challenge. Against this background, measurability is not the biggest challenge for marketing control but rather the clear assignment of causes and effects. To better allocate the specific individual marketing instruments, detailed intermediate targets, such as the level of awareness, visit and contact frequencies or intentions, must be defined (cf. Reinecke 2016, p. 205 f.).

Budgeting is an essential component of the marketing control function. 56% of companies stated that they use the previous year's budget as the basis for marketing the last year's budget, and 52% of budgeting is decided based on management experience or intuition. Combined with the stated savings potential of just under 15 % in the marketing area, target-oriented methods in marketing budgeting in marketing budgeting that go beyond turnover and sales, there are opportunities for optimization (cf. are available (see Reinecke 2016, p. 207). Marketing control instruments can be divided into strategic and operational instruments. Some examples of marketing control instruments are shown in Fig. 1.

According to Reinecke (2016, p. 213), the most successful companies (top 25%) placed particular emphasis on strategic marketing control instruments, such as satisfaction measurements (customers and employees), early warning systems, positioning studies, brand audits and balanced scorecards. Overall, it was stated that the most common competitor/industry analyses, satisfaction assessments and critical performance indicator systems are most frequently used by companies.

Regarding operational marketing control instruments, the respondents most frequently use price and sales success analyses and product and service quality analyses. In the case of marketing accounting instruments, instruments such as budget analyses, contribution margin calculations

(products/projects), investment(products/projects) and investment analyses are regularly used. Contribution margin analysis on the customer or customer lifetime value, on the other hand, only occurs irregularly or rarely. The most successful companies emphasize intensive communication control (especially pre-and post-tests and post-tests), optimization of the media mix, and sponsorship success analyses (see Reinecke 2016, p. 214).

Fig. 1 Examples of strategic and operational marketing control instruments. (Source: Own illustration based on Halfmann 2018; Reinecke 2016).

The division into successful and unsuccessful companies is based on the prioritized dimensions (financial, market- and customer-oriented, employee- and process-oriented, innovation-oriented, and process-oriented, innovation-oriented goals) of the balanced scorecard and the associated target achievement (see Reinecke 2016, p. 209). However, according to Reinecke, there is no need for a cause-and-effect relationship between them. (cf. Reinecke 2016, p. 217).

In summary, the empirical study's results provide information about the status of marketing control in business management practice. On the one hand, there is a high demand for ensuring and measuring the effectiveness and efficiency of marketing. On the other hand, there is insufficient implementation of suitable strategic and operational instruments, especially those that optimize marketing management processes and measures.

In the following, the strategic instruments of SWOT analysis, customer satisfaction evaluation, and the operational control instrument of sponsorship success analysis are used in medical technology companies.

SWOT analysis

Marketing control has long used SWOT analysis for competitive or situational analysis has been using the SWOT analysis for a long time. This includes the internal strengths (strengths and weaknesses of the company, department, or product groups (Fig.2). On the other hand, there is the external analysis. Due to the market conditions, there are (opportunities) and risks (threats) that are defined externally

and, for the most part, cannot be influenced. Preparing a SWOT analysis requires thorough market research with verifiable figures (see Halfmann 2018, p. 39).

A fictitious example of using the SWOT analysis is provided below by the medium-sized Treat Medical, which manufactures and sells reusable surgical grasping forceps and distributes them. The example is based on actual data.

Initial situation: The manufacturer employs 160 people and has sold its medical products in the medical technology sector for nine years. The market entry was made under M.D.D. conditions. The instruments are produced in Germany and have been fully automated. In addition, just-in-time systems were successfully introduced four years ago. Investments have been made in recent years primarily for the continuous optimization of supply chains. On the other hand, investments in digital tools such as CRM systems, social networks, and R&D have not been made. Employee training is provided regularly; Customer satisfaction assessments are also carried out on an ongoing basis.

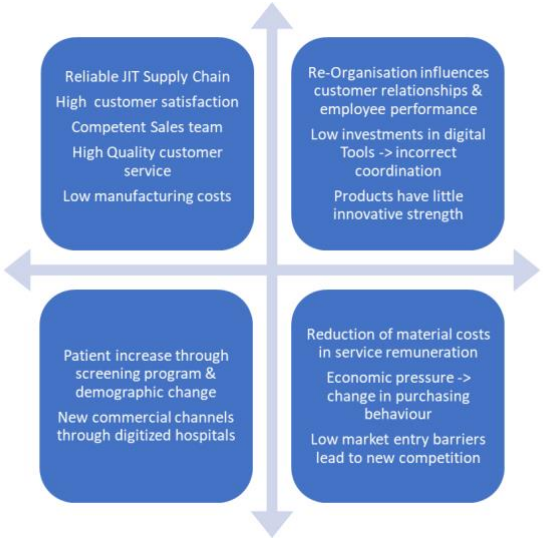

Fig. 2 Example of a SWOT analysis. (Source: authors)

Opportunities arising from the external environment were defined by Treat Medical's management as follows: A newly introduced screening program for the early detection of lung cancer has increased patient care. Consequently, the company has recognized the opportunity to expand its market share and expects an increase in sales potential of 14 %. In addition, the increasing digitalization of hospitals is also opening options for Treat Medical to offer its services via an online platform to reach new customers via an online platform and, if necessary, to sell the products (without sales representatives). As the final pillar of the SWOT analysis, Treat Medical looked at the risks in the workshop. In this case, the hospital structure reform has led to shifts in the D.R.G.s and more challenging conditions for increasing the number of cases. The analysis has revealed that material costs in the relevant therapy areas were reduced by 36 %. As a result, the company expects more arduous price negotiations with service providers and lower competitive prices simultaneously. Another current risk is the low barriers

to market entry, which were classified as another present risk. As a result, it has been among the four new suppliers of surgical grasping forceps on the market in recent months.

The SWOT analysis example described above does not cover the entire spectrum and requires a broader view when explicitly applied. However, this instrument provides control with a basis for obtaining and processing information through in-depth analyses and processing. However, the SWOT analysis also has weaknesses. For example, although the analysis offers room for interpretation, it does not provide any direct recommendations for action (see Grunwald and Hempelmann 2017). The SWOT analysis should ideally be combined with other instruments to counter this criticism. A complementary tool to the SWOT analysis is the competitive analysis, developed by Michael Porter in 2008. This analysis is based on considering five competitive forces, which can have different characteristics. It considers the bargaining power of customers, the threat posed by substitute products, the bargaining power of suppliers, threats from new suppliers and intra-industry competition are analyzed and presented.

Customer satisfaction assessment

In the healthcare sector, customers and their needs are moving to the center of attention as the empirical study by the University of St. Gallen (see Reinecke 2016); successful companies are, therefore, already increasingly relying on regular customer and employee satisfaction measurements. The results identify errors or weaknesses in the process and act accordingly to ensure the company's success (see Föhrenbach 1995). In addition, customer satisfaction ratings help to allocate the effectiveness of marketing or sales activities better administer marketing or sales activities.

Medical technology manufacturers have various possibilities for determining customer satisfaction. On the one hand, marketing control can conduct analyses based on complaints, customer problems, or employee assessments. On the other hand, critical figures on the repurchase rate of customers or sales trends of individual products are indicators of customer satisfaction (cf. Manser, n.d.).

Direct customer surveys are subjective but informative methods. Some of the most common methods are:

- Customer Satisfaction Score (C.S.A.T.) - measuring satisfaction using a Likert scale from 1-5, where 5 expresses the highest customer satisfaction.
- Customer Effort Score (C.E.S.) - customer survey on how much effort was required to solve a problem, the order was placed, or a complaint was recorded could be made. A 5 or 7 Likert scale is used here. The higher the value, the greater the effort for the customer.
- Net Promoter Score (N.P.S.) - The survey refers to whether customers recommend they would recommend the company or product/service to others. The standard here is a 10-point Likert scale, where values between 1-6 are rated as critics and 9-10 as promoters are rated.

- Personal interview - As a rule, a personal interview is conducted by employees of the company performed by employees of the company.

In medical technology, there are several essential players along the supply and sales process, making determining customer satisfaction more challenging than in industries with a specific end customer (e.g. cell phones). Even if the patient is at the center of care and the quality of the outcome (successful (successful therapy) is at the forefront, for medical technology developers, the product's user is the primary customer. In addition, other decision-makers within the private and public hospital operators (e.g. purchasers) must also be considered and taken into account.

Even if the patient is the focus of the care and, in the end, the quality of the result (successful therapy) is the focus for medical technology manufacturers, the product's user is the primary customer. Other decision-makers within the private and public hospital authorities (e.g., buyers) also exist.

Medical technology can also use the four previously listed methods for determining customer satisfaction. However, some of the methods include specific limitations. The C.S.A.T. measures doctors' satisfaction with the services offered, products, services or advice from the field staff. A limitation of the data is that it is due to the ordinal scaling. There are no meaningful findings between a rating of four or five. In addition, no new needs can be identified due to the query using a Likert scale to be determined.

The continuous C.E.S. survey measures the effort required by the customer (such as a doctor or nurse) to be served to solve a problem or make a complaint. A high effort rate, synonymous with poor results, is implied, for example, possible quality problems with certain medical products or deficiencies in customer service. Low expenditure rates, on the other hand, indicate high customer satisfaction because issues are quickly identified and resolved. Against this background, findings from the C.E.S. method are essential for marketing control and valuable for analyzing individual processes and making suggestions for optimization. Quality problems with products such as implants, Ultrasound devices or surgical instruments must be detected and processed promptly to avoid significant image and economic damage. The advantage of this method is that only specific areas are covered, and not a holistic overview is provided. For this reason, the C.E.S. is not a reliable source for getting an overall picture of customer satisfaction.

The N.P.S. method is one of the most well-known methods for measuring customer satisfaction. In medical technology, promoters, critics, and medical opinion leaders are crucial to understanding and recognizing needs. Regular N.P.S. surveys along the product life cycle provide opportunities for marketing optimization at every stage. If N.P.S. analysis is regularly used as a tool, it must be based on a sufficiently large sample and short periods between collection and analysis.

Another method for measuring customer satisfaction is using personal conversations. Many medical technology companies maintain close customer relationships with users or buyers. The private

discussion enables it to react directly to dissatisfied customers and analyze deeper needs. However, the perception of customer satisfaction is often subjective. It carries risks that customers in direct contact will have negative experiences with the product and do not want to name the respective company or its employees.

In summary, it can be said that companies can proceed with a method for measuring customer satisfaction for marketing control in medical technology. In addition to analyses based on internal data, the insights should be linked to external ones. Data is compared. Several different methods are available for this to compensate for the limitations of individual methods and thus provide a clear picture to maintain customer satisfaction.

Sponsorship success analyses

Successful companies regularly use operational marketing control. An essential instrument is the sponsorship success analysis. Sponsorship is one of several Marketing communication tools (cf. Bruhn 2009, p. 3). According to a communication study in 2015, in 461 companies in Germany, more than 50 employees were interviewed (CATI or online). The share of the sponsorship budget at €2.58 billion was around 9% of the total communications budget. In addition, the "direct business communication" budget was just under 18%. This includes trade fairs, congresses, events and brand parks and is closely connected to sponsorship. This makes them use measures on the overall significance of sponsorship as a communication tool and a significant contribution (cf. Zanger 2016, p. 13 f.). Given the high relevance of sponsorship activities, monitoring effectiveness and efficiency through marketing control is essential. According to Schwizer and Reinecke (2017, p. 25), sponsorship can be divided into three phases:

1. Sponsorship commitment (acquisition of rights),
2. Sponsorship activation as well
3. Implementation and optimization.

Each of the three phases must be accompanied by control. Before deciding on one, the different options are for a specific sponsorship commitment that aligns with company goals. The fit of the sponsorship influences, for example, goals such as image or level of awareness. Those met in advance. Considerations help improve the effectiveness and efficiency of the activities analyzed. The activation phase begins after the sponsorship contract has been concluded. In this phase, all measures are taken to ensure the sponsor's defined message is brought to the target group. Ideally, this implies that the message is distributed before the sponsorship period. Tasks of sponsorship control include budgeting and resource planning before starting the activation phase (human and financial costs). Implementation and continuous improvement the activation measures require a lot of resources but deliver clear activation goals with key performance indicators (KPI) and the opportunity to benefit from

standing out from the competition. As long as it is strategic as a marketing communication tool, the success measurement includes many planned communication measures (cf. Bruhn 2009, p. 3).

The third and final phase is implementation and optimization to prove the effectiveness of the sponsorship measures. This occurs during this period, measuring success based on the previously defined KPIs. If the measures are over a more extended period, they can be done via permanent or recurring measurements. Measures have already been optimized. When measuring the influence of sponsorship measures on product sales, it should be noted that several factors influence the purchase decision. Sponsorship control should focus on the KPIs directly affected by sponsorship commitment influence (e.g., range).

In medical technology, sponsorship is used as a marketing communication tool. Sponsorships can take place at different levels. According to an empirical study from 2019 involving 233 American marketing managers, where healthcare companies took part, the average marketing budget was $10.49 million. 80% of those surveyed came from companies with annual sales of Make $500 million or more. That leaves a marketing budget of approximately 2% of total sales. Broken down to medical technology companies lay. However, the budget made available at $7.8 million for pharmaceutical ($11.56 million) or biotech manufacturers ($9.05 million) is significantly lower (cf. Daniels 2019). When looking at the budget allocation, it is striking that medical technology companies have the largest marketing budget for "professional meetings/conferences" and "Sales Representatives". Spending of 14.7% for "Professional Meetings/Conferences" is almost three times as high as in the areas of pharmaceuticals (6.3%), biotech (4.9%), and Diagnostics (5.7%) (see Daniels 2019). The American healthcare market is subject to different framework conditions and is designed differently than Germany's. Nevertheless, the expenses can be in the range of "Professional Meetings/Conferences", which is a trend for the German market and especially for sponsorship activities in the field of education (training events and congresses), as these two marketing measures are closely linked in medical technology.

Further information about the selected German sponsorship commitments Healthcare company delivers the study published in 2018 (Desktop Research) by Research Tools (2018). In this study, 692 sponsorship projects out of 10. Further information about the selected German sponsorship commitments Healthcare company delivers the study published in 2018 (Desktop Research) by Research Tools (2018). This study examined 692 sponsorship projects from ten German pharmaceutical manufacturers, such as Astra Zeneca, Boehringer Ingelheim, Merck and Bayer Healthcare, analyzed.

According to the analysis, sponsorship budgets are mainly for social projects (49%), closely followed by education and a long way for Sports sponsorships used. Sponsorship opportunities in culture and Environment were only used very rarely. Regarding the sponsored projects at Social and Education, there are health-related foundations and associations as well as medical ones.

Symposiums and congresses account for around 70% of the total activities of pharmaceutical industry manufacturers, clearly in focus. In addition, a long-term commitment could be made to companies, either several times a year or permanently (33% of projects). The sponsorship commitments are identified (see Research Tools 2018).

There is little published literature on detailed sponsorship commitments from German medical technology manufacturers. The comparison of the above American study from MM&M/Deloitte (cf. Daniels 2019) to the results of the study of research tools from the sponsorship commitment of German healthcare companies suggests that German medical technology companies have a similarly high-rate Budget portion for sponsorships.

It is questionable which crucial task supports medical technology companies' marketing control. Based on the knowledge gained that sponsorship acquisition is often based on foundations, associations, symposiums, and congresses, a fictitious example from medical technology is given below for the practical implementation of sponsorship control. In this example and the elemental analysis, we only focus on the content of the communication instrument of sponsorship and not its focus on legal, regulatory, and ethical frameworks.

Example

The company Heile-Gut GmbH has been in the healthcare sector as a wound care manufacturer for 12 years and employs 40 staff. Company management was in place at the beginning of the product launch of an innovative wound dressing (significant). According to the study, the product offers substantially added value to potential target groups, wound managers, and surgeons. Suppose the wound dressing remains in place for a more extended period. In that case, there will be fewer patients (higher intake volume) and improved handling (sticks less often glove of the user and reduces material consumption) with greater cost-effectiveness compared to competing manufacturers. The wound care manufacturer has set itself the following goals:

- Increase in awareness and utility of the new wound dressing by 25% and
- Increase in product sales by 30%.

There is a wide range of sponsorship opportunities for the manufacturer. Various congresses and symposiums were held in advance using a scoring model. Criteria included: number of participants and professional group, type the department, reach, scientific content, and sponsorship package offers, which were aligned with the company's own goals. Based on this analysis, The choice was to participate in the wound congresses I.W.C. and DeWU.

After purchasing the sponsorship commitment, marketing developed the activation measures described in Fig. 3 about the sponsorship and the associated messages to make the target group (wound managers) visible.

The measures include, among others, creating a congress concept, publishing an article in a specialist journal before the congress takes place, and the announcement of sponsorship of social media channels. Sponsorship control takes place during the activation phase. Budget monitoring is carried out, and individual measures are constantly monitored for effectiveness and efficiency checked to achieve improvements. In the implementation and optimization phase, the focus is on monitoring success. Predefined KPIs are helpful for analysis.

The company has visitor numbers as a quantitative KPI and visitor surveys as a qualitative KPI. The measurements of the number of visitors at the stand and the lectures provide insights into the effect of perception. You will be considered by the company, as well as those of the competitors and the total number of visitors to the congresses. Stand surveys serve as a qualitative instrument to determine whether and how the desired message reaches the target audience. In the end, the wound care company was able to in terms of effectiveness, we found that awareness increased by 37% and Sales increased by 12%. In terms of efficiency, resource consumption was immense for headcounts and budgets. 65% of marketing resources were used for sponsoring activities are used. These measures had to be taken elsewhere, supporting direct sales measures, which can be significantly reduced.

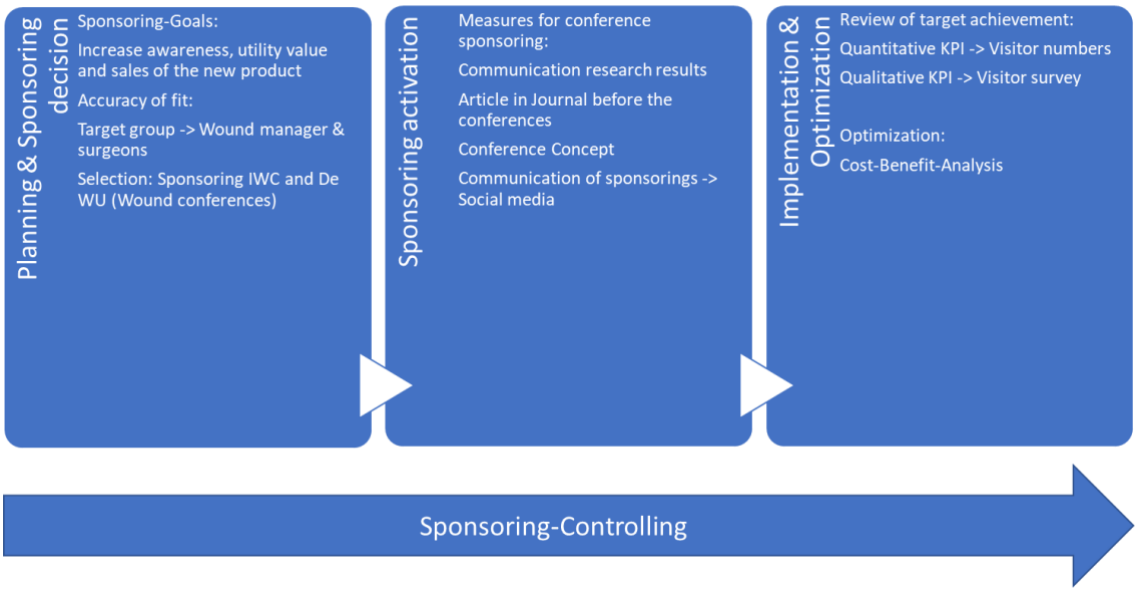

Fig. 3 Example of sponsorship control. (Source: Own illustration based on Schwizer and Reinecke 2017, p. 28)

The company management is aware that many factors that are difficult to detect influence purchasing decisions. In addition to sales growth, marketing controlling also sets targets that are not directly relevant to sales, such as increasing brand awareness and customer perception, to achieve the objectives. In summary, it can be stated that the pursuit of Resources is necessary for the accompanying control due to the high status of sponsoring as a communication tool within healthcare marketing. Through professional planning, analysis, implementation, and control of activities, a

successful assessment of the effectiveness and efficiency of sponsorship is possible (although not 100%); this ensures the optimization of future sponsorship engagements. To do this, the relevant goals must be defined in advance and based on them. Compare key performance indicators during the process and afterwards. The challenge here is for companies to collect data, such as customer conversations during/after congresses, or to establish links between the various measures, such as app/website visits, participation in scientific lectures and customer visits by the sales force. These challenges make it difficult for the sponsor to measure the impact in relation to the resources provided and the previously defined target achievement. There are various software tools on the market in the form of customer relationship management systems, such as Salesforce, LinkedIn or Analytics 360 (Google), which support such analyses.

2.3 Digitalization and Big Data as Possibilities Expanded Marketing Control.

As described at the beginning, digitalization is a key to improved care in the healthcare system. The introduction of the health card in 2003 and the electronic patient files in 2008 should push digitalization forward positively. Digitalization aims to make it easier or partially automate the exchange of information to connect the different care sectors. According to a global study by the Bertelsmann Foundation (2018), Germany was ranked 16th out of 17 in the digital health index. Top-ranked countries, such as Estonia, Canada, and Denmark, are using electronic medical records or prescriptions that have already been implemented. The first approaches to digitalization were also seen in German patient care, but the skeptical attitude of the actors involved proved to be a decisive Hurdle. Digitalization requires new processes and institutions to be connected, but 94% of hospitals still communicate medical practices primarily in paper form (cf. Ex and Amelung 2019, p. 111 f.). These numbers align with the analysis from 2015 (cf. Digital Intelligence Institute 2015, P. 11), in which more than 2/3 of all facilities use medical processes with 50% or more in paper form. Even if the need for digital change is high, the below-average economic index results are reflected in the company's digitalization strategies again.

More than half of the medical technology pursued does not have a clearly defined digitalization strategy and investment; relative to total spending, relatively small amounts are invested in digital projects (see Dispan 2020, p. 55). Although the current status paints a rather negative picture of digitalization, it offers excellent opportunities for the healthcare system. Whether in Healthcare, research or prevention and diagnosis of diseases, in each area, Optimizations can be achieved through the large amount of data generated.

On the other hand, it should not be forgotten that when dealing with sensitive patient-related issues, Health data requires high standards of data protection and I.T. security by the groups of actors involved (cf. Blachetta 2016, p. 25). With the increasing volume of structured and unstructured data in the healthcare sector (see W. Raghupathi & V. Raghupathi 2014) and the need for fast and meaningful

evaluations, big data, and business analytics (mostly based on big data) are becoming increasingly important. Big data analytics is an achievable business value.
This added value for companies in healthcare can be divided into five categories:

- I.T. infrastructure advantages,
- Operational benefits,
- Organizational benefits,
- Management benefits and
- Strategic benefits

However, due to the low adoption of information technology (IT) in healthcare, there are currently few primary data sets available to analyze and evaluate important aspects such as organizational performance (cf. Wang et al. 2018). In contrast to "eHealth" applications, which implement networking and communication between organizations, sensors, people and IT systems in the healthcare sector, business analytics applications based on big data can convert analyses, evaluations, and aggregations of data into decision-relevant information (cf. Blachetta 2016, p. 53).
Ultimately, healthcare big data offers a variety of data sources. Summarized, they can be clustered into seven sources:

1. Medical data,
2. Public health data,
3. Insurance data,
4. Research data,
5. Individual data generated by users,
6. Pharmaceutical/medical technology data as well, and
7. Non-classical health data.

Various technologies and storage systems can be used to analyze data from different data sources using business analytics and generate decision-relevant information. Ultimately, users want to gain insights for four objectives: reporting, monitoring, evaluation, and forecasting.
In addition to fields of application such as health prevention and performance and quality assessment, business analytics also provides important insights into process improvements. Organization-related data, such as internal billing data or data from the company's social networks, can be analyzed and prepared as information for the relevant decision-makers in order to identify areas for optimization (see Blachetta 2016, p. 58 f.).

Companies that already work with large amounts of data in internal processes can be used during the research process or market launch, for example, creating accurate world data analyses on the effectiveness of medications. These analyses can be used as risk-benefit profiles to reduce market launch costs and influence price negotiations (cf. Blachetta 2016, p. 65).

Companies that already work with large amounts of data in their internal processes can use real-world data to analyze the effectiveness of drugs during the research process or market launch, for example. These analyses can be used as risk-benefit profiles to reduce market launch costs and influence price negotiations (see Blachetta 2016, p. 65). In a 2019 survey, 82% of companies that are members of the German Medical Technology Association stated that they already use digital solutions for process and product improvements. However, only 13% of companies already use big data applications (see BVMed 2020, p. 13).

In conjunction with marketing controlling tools, such as customer satisfaction measurements or sponsorship success analyses, digitalization and big data applications in particular can solve many challenges. Currently, personal interaction channels dominate the customer relationship. This is particularly evident when it comes to complex issues, such as the satisfaction of individual customer needs through the added value of a specific medical technology product. Along the customer sales cycle, a wide variety of channels are used for measuring customer satisfaction or monitoring success in the form of perception and attitude effects. Some of these channels include online and offline surveys, telephone interviews as well as direct or indirect (via third parties) surveys.

Due to the high number of different interaction channels, all of which are in competition with each other, there is considerable potential for conflict. These conflicts result in piecemeal information assignments and connections (see Avramakis 2020, p. 228 f.).

Even if complex products or services continue to require social interactions, the use of digital platforms (e.g. LinkedIn), social networks such as Facebook and CRM tools such as Salesforce can be used to collect data on customer behavior, reactions or wishes. Big data applications are used to read and analyze data from social networks, video portals in different languages and Salesforce entries in a relatively short time. The findings help the company concerned to respond to customer needs at short notice, develop innovative products and optimize sponsorship commitments. In addition, big data applications overcome time challenges such as the net promoter score method (time between collection and analysis) and have a strong impact on optimized customer satisfaction measurements.

Further application and optimization options, such as product or process optimization through machine-to-machine (M2M) learning or an expanded information supply through Artificial Intelligence (A.I.) applications, are due to the complexity of these topics, which will not be discussed further here.

3 Conclusion

German medical technology companies have been one of the most robust growing industries since 2010. Despite above-average EBIT margins compared to other Industries, they face continuous change and significant challenges. New legal and regulatory frameworks ensure increased and cost-related demands on manufacturers and their customers' medical devices. In connection with the economic challenges faced by service providers, such as hospitals, medical technology companies must consider new solutions. Old marketing concepts need to be rethought and reviewed with new concepts such as SAVE. A customer-oriented focus, tailored to recognizing and satisfying customer needs and clearly highlighting the company's own added value, can also provide advantages in a highly competitive environment.

To remain competitive, the effectiveness and efficiency of market and customer-oriented marketing activities must be continuously ensured. For this reason, it will be crucial for medical technology companies in the future to use marketing controlling to support planning, analysis, and implementation. Two instruments that can be used as cornerstones of marketing controlling for medical technology companies are customer satisfaction evaluation and sponsorship success analysis. As a strategic controlling instrument, many current evaluation methods do not provide sufficient information about customer satisfaction on their own. To obtain decision-relevant information in the shortest possible time, investments in digital platforms and social networks as well as the use of big data applications are indispensable. This means that various data sources, such as surveys, social networks, or CRM systems, can be used together and provide marketing controlling with analyses of customer satisfaction and subsequently decision-relevant information on ways to optimize processes or medical products. The situation is similar with sponsorship success analysis. While a significant proportion of the overall budget is spent on sponsorship commitment in medical technology, it is essential to accompany the process at every stage with sponsorship controlling in view of the financial challenges expected in the coming years. The measurability of economic goals and success factors, such as image gain or perception and attitude effects, is raised to a new level by the usage of digital CRM systems and the application of big data analytics. From a marketing controlling perspective, the use of these tools also makes it possible to provide and justify resources for process improvements.

Overall, the findings described above suggest that medical technology companies will no longer be competitive in the future without investing in digital technologies. Particularly with regard to efficient marketing controlling, digitalized companies have the opportunity to optimize processes and identify customer needs at an early stage using processed analyses from various data sources.

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