J-A25015-02

2002 PA Super 416

WILLIAM J. STALSITZ AND ELVIRA A. STALSITZ, H/W,	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
Appellants	:	
v.	:	
THE ALLENTOWN HOSPITAL, LEHIGH VALLEY HOSPITAL, INC., LEHIGH VALLEY HOSPITAL, INC., A HEALTH EAST HOSPITAL, GARY G. NICHOLAS, M.D., ALAN BERGER, M.D., MEDICAL IMAGING OF LEHIGH VALLEY, P.C. AND JAMES JAFFE, M.D.,	:	
Appellees	:	No. 2057 EDA 2001

Appeal from the Order June 29, 2001
In the Court of Common Pleas of Lehigh County
Civil at No. 94-C-13

BEFORE: STEVENS, KLEIN, and TAMILIA, JJ.

OPINION BY STEVENS, J.: Filed: December 31, 2002

¶ 1 William and Elvira Stalsitz appeal from the denial of their motion for a new trial and subsequent entry of judgment in favor of the Lehigh Valley Hospital (LVH), Medical Imaging of Lehigh Valley (Medical Imaging), and doctors Gary Nicholas, Alan Berger, and James Jaffe.[1] We affirm.

¶ 2 This appeal arises from a medical malpractice action filed by Appellants in regard to treatment received by William Stalsitz for blood clots in his right leg. In January 1992, Mr. Stalsitz was admitted to LVH complaining of pain in his legs and feet. Dr. Nicholas, a peripheral vascular

[1] Appellants originally brought suit against additional defendants, but only those named remain as parties.

surgeon, evaluated Mr. Stalsitz and consulted with Dr. Jaffe, an interventional radiologist. Subsequent tests showed a blood clot behind Mr. Stalsitz's right knee joint and additional clots below his right knee. Doctors Nicholas and Jaffe determined that lytic therapy, which involves the administration of medication directly into the blood clot, was the most appropriate way to treat Mr. Stalsitz's condition. At the time, Dr. Jaffe was involved in a study being performed to evaluate the use of low doses of Recombinant Tissue Plasminogen Activator (TPA) in lytic therapy to dissolve clots in the lower extremities.[2] Dr. Jaffe explained the procedures involved in the study to Mr. Stalsitz, answered his questions, and had Mr. Stalsitz sign a consent form for participation in the study.

¶ 3 The study involved infusing two milligrams of TPA per hour through a catheter placed in the blood clot, until forty milligrams had been infused. Angiograms were to be performed four hours into the procedure, and thereafter at eight-hour intervals from initiation of the therapy, until the study concluded at twenty hours. In Mr. Stalsitz's case, the TPA therapy began at 11:00 a.m. When the four-hour angiogram was performed, it revealed that much of the clot still remained and that that Mr. Stalsitz suffered from arteriosclerosis (the narrowing of arteries, which limits blood flow). The TPA therapy continued on schedule, but another angiogram was

[2] TPA had regularly been used to dissolve clots in coronary arteries. This particular study was being conducted to determine its efficacy in the lower extremities.

not performed until twenty hours after the therapy began. It revealed that the TPA therapy had been successful with regard to the clot behind Mr. Stalsitz's knee, but also that the arteriosclerosis detected by the four hour angiogram was still present.

¶ 4 Although the TPA study was complete, because of the remaining problems, Dr. Jaffe consulted Dr. Berger, Dr. Nicholas' partner, and the two decided that an angioplasty[3] should be performed to address the arteriosclerosis and prevent reformation of the clot that had been successfully dissolved by the TPA therapy. Dr. Jaffe performed the angioplasty, and an angiogram taken afterward showed good circulation to the peroneal artery, but also a blood clot in the area of Mr. Stalsitz's ankle, preventing blood flow to his right foot. Doctors Jaffe and Berger then contacted the head of the TPA study, and decided to administer additional TPA to dissolve the newly discovered clot. When blood flow to Mr. Stalsitz's foot was achieved, the TPA was discontinued. Thereafter, however, Mr. Stalsitz suffered edema in his right leg, and he was treated for compartment syndrome, although not before muscle tissue in his right leg was destroyed.

¶ 5 Appellants filed their original complaint against Appellees in April 1994, alleging various counts of negligence and, in count five, a lack of informed consent claim in connection with the TPA therapy and the performance of the angioplasty.

[3] An angioplasty involves the insertion of a balloon to widen an artery.

¶ 6 In response to preliminary objections, Appellants filed an amended complaint in May, 1994, and a second amended complaint in June, 1994, which continued to allege lack of informed consent in count five.[4] Third, fourth, and fifth amended complaints were filed in July, August, and September of 1994, again containing a common law allegation of lack of informed consent, but also adding a claim that informed consent was necessary under Federal Food and Drug Administration (FDA) regulations.

¶ 7 Appellees filed preliminary objections to the amended complaints, demurring to count five on the grounds that, *inter alia*, Appellant's claim regarding FDA regulations was not previously averred and its inclusion in the amended complaints violated the applicable two-year statute of limitations for civil action set forth by 42 Pa.C.S.A. § 5524. On March 14, 1995, the trial court granted Appellees' preliminary objections to count five of Appellant's fifth amended complaint. A sixth amended complaint followed, and a jury trial was held from March 16, 2000 through March 30, 2000.

¶ 8 On March 31, 2000, the jury reached a verdict, concluding that Doctor Jaffe and the Lehigh Valley Hospital were negligent in their care of Mr. Stalsitz, but that their negligence was not a substantial factor in increasing the risk of harm to him. The jury found no negligence on the part of the other Appellees. Appellants filed motions for post-trial relief on April 10, 2000, requesting a new trial on various grounds and judgment

[4] Appellants filed their amended complaints before the trial court dealt with

notwithstanding the verdict on the ground that the verdict was against the weight of the evidence.

¶ 9 Appellant's post-trial motions were denied by the trial court on June 29, 2001, judgment was subsequently entered in favor of Appellees, and Appellants filed the appeal currently before us on July 27, 2001, asserting that (1) the trial court should have ordered a new trial because it was error to grant Appellees' preliminary objections to Appellants' informed consent claim, (2) the trial court should have ordered a new trial because it was error to fail to preclude certain evidence at trial as irrelevant and prejudicial, as well as beyond the scope of the expert report; and (3) the trial court should have ordered a new trial because it was error to admit certain testimony at trial.[5]

> We will reverse a trial court's decision to deny a motion for a new trial only if the trial court abused its discretion. ***See Harman v. Borah***, 562 Pa. 455, 756 A.2d 1116, 1121-1122 (Pa. 2000). We must review the court's alleged mistake and determine whether the court erred and, if so, whether the error resulted in prejudice necessitating a new trial. ***See id***. at 1122-1123. If the alleged mistake concerned an error of law, we will scrutinize for legal error. ***See*** [***id.***] at 1123. Once we determine whether an error occurred, we must then determine whether the trial court abused its discretion in ruling on the request for a new trial. ***See id***. "An abuse of discretion exists when the trial court has rendered a judgment that is manifestly unreasonable, arbitrary, or capricious, has failed to apply the law, or was motivated by partiality, prejudice, bias, or ill will." ***Id***. at 1123.

Appellees' preliminary objections.

[5] Each of these allegations has been preserved by inclusion in Appellants' post-trial motions. Appellants do not challenge the trial court's refusal to grant judgment notwithstanding the verdict.

Petrecca v. Allstate Insurance Company, 797 A.2d 322, 324 (Pa. Super. 2002). With this guidance, we examine Appellant's claims individually.

¶ 10 Appellants first assert that they are entitled to a new trial because the trial court erred in granting Appellees' preliminary objections in the form of a demurrer to the informed consent count of Appellants' fifth amended complaint. A brief discussion of the law of informed consent is helpful to the resolution of this issue.

¶ 11 "It has long been the law in Pennsylvania that a physician must obtain informed consent from a patient before performing a surgical or operative procedure." ***Morgan v. MacPhail***, 550 Pa. 202, 205, 704 A.2d 617, 619 (1997) (*citing* ***Sinclair v. Block***, 534 Pa. 563, 633 A.2d 1137 (1993), ***Gray v. Grunnagle***, 423 Pa. 144, 223 A.2d 663 (1966)). Under Pennsylvania's common law doctrine, however, informed consent has not been required in cases involving non-surgical procedures.[6] ***Id***. This distinction has been upheld because Pennsylvania has grounded the doctrine of informed consent "upon the legal theory that the performance of a medical procedure without a patient's informed consent constitutes a technical assault or battery." ***Stover v. Association of Thoracic and Cardiovascular Surgeons***, 635 A.2d 1047, 1053 (Pa. Super. 1993) (citation omitted).

> Our Supreme Court has consistently held that a physician performing a surgical procedure must obtain informed consent

[6] In addition to the surgical/non-surgical differentiation, the obligation to obtain informed consent is generally imposed only on physicians, not hospitals, as we will discuss *infra*.

> from the patient. Without such consent, a "touching" is an unauthorized, technical battery, and an actionable tort. ***Gray v. Grunnagle***, 423 Pa. 144, 223 A.2d 663 (1966); ***Smith v. Yohe***, 412 Pa. 94, 194 A.2d 167 (1963).

Gentzler v. Atlee, 660 A.2d 1378, 1382 (Pa. Super. 1995). As the Pennsylvania Supreme Court recently explained in ***Valles v. Albert Einstein Medical Center***, 805 A.2d 1232 (Pa. 2002):

> In a claim alleging lack of informed consent, it is the conduct of the unauthorized procedure that constitutes the tort. ***Moure v. Raeuchle***, 529 Pa. 394, 604 A.2d 1003, 1008 (Pa. 1992). A claim of a lack of informed consent sounds in the intentional tort of battery because an operation performed without the patient's consent is deemed to be the equivalent to a technical assault. ***Smith v. Yohe***, 412 Pa. 94, 194 A.2d 167, 174 (Pa. 1963). To obtain a patient's informed consent, doctors must provide patients with "material information necessary to determine whether to proceed with the surgical or operative procedure or to remain in the present condition." ***Duttry v. Patterson***, 565 Pa. 130, 771 A.2d 1255, 1258 (Pa. 2001) (quoting ***Sinclair by Sinclair v. Block***, 534 Pa. 563, 633 A.2d 1137, 1140 (Pa. 1993)). This information must give the patient "a true understanding of the nature of the operation to be performed, the seriousness of it, the organs of the body involved, the disease or incapacity sought to be cured, and the possible results." ***Id***. (quoting ***Gray v. Grunnagle***, 423 Pa. 144, 223 A.2d 663, 674 (Pa. 1966)). While doctors are not required to disclose "all known information," they are required to "advise the patient of those material facts, risks, complications and alternatives to surgery that a reasonable person in the patient's situation would consider significant in deciding whether to have the operation." ***Gouse v. Cassel***, 532 Pa. 197, 615 A.2d 331, 334 (Pa. 1992) (emphasis omitted).

Valles, 805 A.2d at 1237.

¶ 12 On November 26, 1996, the Pennsylvania Legislature amended the Health Care Services Malpractice Act (the Act) to substantially codify the

common law doctrine of informed consent.[7] 40 P.S. § 1301.811-A. In addition, the Act expanded the doctrine to include medical procedures previously excluded under the common law of informed consent, including radiation, chemotherapy, and non-surgical related blood transfusions. 40 P.S. § 1301.811-A(a)(2)-(3).[8] The Act has been interpreted narrowly by the Pennsylvania Supreme Court in ***Morgan***, which appears to indicate that apart from the statutorily created exceptions, the surgery requirement will remain. ***Morgan***, 550 Pa. at 207 n.6, 704 A.2d at 620 n.6.

¶ 13 ***Morgan***, like the instant case, involved procedures performed before the effective date of the Act. In ***Morgan***, the Pennsylvania Supreme Court considered whether the injection of a long acting steroid and the injection of a local anesthetic constituted a surgical procedure requiring informed

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[7] The Healthcare Services Malpractice Act states:

> (a) Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:
>
> (1) Performing surgery, including the related administration of anesthesia.
>
> (2) Administering radiation or chemotherapy.
>
> (3) Administering a blood transfusion.
>
> (4) Inserting a surgical device or appliance.
>
> (5) Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner.

40 P.S. 1301.811-A(a)(1)-(5), effective January 25, 1997.

[8] The provisions of the Act are inapplicable to the instant matter, however, as they became effective after the procedures at issue here. ***Duttry***, 565 Pa. at 135 n.1, 771 A.2d at 1258 n.1; ***Morgan***, 550 Pa. at 207 n.6, 704 A.2d 620 n.6.

consent. In characterizing a surgical or operative procedure, the Court explained as follows:

> Neither the Pennsylvania legislature nor courts have defined surgical or operative procedure; however, "operate" is defined in Taber's Cyclopedic Medical Dictionary 1256 (16th ed. 1989) as "to perform an excision or incision, or to make a suture on the body or any of its organs to restore health." "Surgery" is defined in Black's Law Dictionary 1442 (6th ed. 1990) as "that branch of medical science which treats of mechanical or operative measures for healing diseases, deformities or injuries." "Operation" is defined as "an act or succession of acts performed upon the body of a patient, for his relief or restoration to normal conditions, by the use of surgical instruments as distinguished from therapeutic treatment by the administration of drugs or other remedial measures." Black's Law Dictionary 1092 (6th ed. 1990).

Morgan, 550 Pa. at 206, 704 A.2d at 619. The Court then concluded that neither procedure in question fell within the definition of surgical or operative procedures because:

> [N]either involved an excision or incision or the use of surgical instruments; rather, they involved the therapeutic administration of drugs. In fact, the procedures are more closely analogous to the introduction of medication through an intravenous needle or line because the instant procedures and the intravenous use of medication both involve the use of needles to inject medication rather than the use of surgical instruments. Courts applying Pennsylvania law have not required informed consent in cases involving intravenous administration of medication. ***Wu v. Spence***, 413 Pa. Super. 352, 605 A.2d 395 (1992) (no informed consent needed for intravenous administration of antibiotics). ***Accord***, ***Karibjanian v. Thomas Jefferson University Hospital***, 717 F. Supp. 1081 (E.D.Pa. 1989)(doctrine not applicable to intravenous administration of prescription drugs).

Id. 550 Pa. at 206-207, 704 A.2d at 619-620.

¶ 14 Therefore, when dealing with cases involving procedures performed before the 1996 amendment of the Healthcare Services Malpractice Act, informed consent claims sound in battery, and informed consent applies only to cases involving surgical or operative procedures, which do not include the intravenous administration of drugs.

¶ 15 Additionally, as we noted above, the duty to obtain a patient's informed consent is generally limited to the surgeon performing the operative procedure. ***Valles***, ***supra***; ***See also Gentzler***, 660 A.2d at 1382 (In Pennsylvania, only surgeons who actually perform the operative procedures have the duty to warn patients of risks and thus obtain informed consent.). In ***Valles***, the Pennsylvania Supreme Court addressed the question whether a hospital can be held vicariously liable as a matter of law for its employee-physicians failure to obtain informed consent. ***Valles***, 805 A.2d at 1235-1236. The Court reasoned that:

> Even if we were to assume arguendo that [the physician] was an employee, Appellant is still not entitled to relief. We reach this conclusion since we find that a battery which results from a lack of informed consent is not the type of action that occurs within the scope of employment. In our view, a medical facility cannot maintain control over this aspect of the physician-patient relationship. … Thus, we hold that as a matter of law, a medical facility lacks the control over the manner in which the physician performs his duty to obtain informed consent so as to render the facility vicariously liable.

Id. at 1239. Although not applicable in ***Valles***, the Supreme Court mentioned an exception to the rule that a hospital cannot be held vicariously

liable for a physician's failure to obtain informed consent. ***Id***. at 1236 n.9 (*citing* ***Friter v. Iolab Corp.***, 607 A.2d 1111 (Pa. Super. 1992)).

¶ 16 ***Friter*** concerned a hospital that was involved in a clinical investigation for the Federal Drug Administration. On November 22, 1982, Dr. Kenneth Michaile implanted an Iolab Model 91Z anterior chamber intraocular lens into Frederick Friter's left eye following cataract surgery at Wills Eye Hospital. ***Friter***, 607 A.2d at 1111. The lens was the subject of a clinical investigation to determine its safety. ***Id***. Both Dr. Michaile, as a registered investigator for Iolab, and Wills Eye Hospital, as an approved institution for conducting experimental studies, were bound by FDA regulations to obtain an informed consent from any patient undergoing experimental treatment as part of the study. ***Id***. However, Friter was never informed, prior to surgery, that he was about to become a participant in the clinical investigation or that an unapproved medical device was to be implanted in the interior portion of his eye as a substitute for his natural lens. ***Id***. at 1111-1112. As a result of the surgical implantation of the lens, Friter suffered numerous complications. ***Id***. at 1112. On appeal to this Court, we were asked to determine "whether appellants, proceeding against the hospital under a theory of lack of informed consent, pled and proved facts sufficient to justify the jury's verdict against Wills Eye Hospital, given that this Commonwealth, heretofore, has never recognized an informed consent action against a hospital." ***Id***. After initially noting that "our research failed to uncover any Pennsylvania

authority for imposing an independent duty on a non-physician to obtain a patient's informed consent," ***Id***. at 1113, the ***Friter*** court carved out an exception to the general rule, holding that the hospital was directly liable for failing to obtain Friter's informed consent because it had specifically assumed the duty to obtain consent as a part of the clinical investigation conducted under the auspices of the FDA. ***Valles v. Albert Einstein Medical Center***, 758 A.2d 1238, 1243 (Pa. Super. 2000) (*affirmed by* 805 A.2d 1232 (Pa. 2002) (*citing* ***Friter***, 607 A.2d at 1113-1115). The hospital thus assumed an independent duty that it would not ordinarily bear. ***Watkins v. Hospital of the University of Pennsylvania***, 737 A.2d 263, 269-270 (Pa. Super. 1999) (*citing* ***Friter***).

¶ 17 Based on the above, the general rule is that informed consent only applies to surgical procedures, and only to the physicians performing those procedures. With this as our foundation, we turn to Appellants' allegation that they had a valid claim for lack of informed consent and, therefore, that it was error for the trial court to grant demurrers to the informed consent count of their complaint.

¶ 18 In reviewing a trial court's decision to grant a demurrer, all material facts set forth in the complaint and all inferences reasonably deducible therefrom are accepted as true. ***Estate of Witthoeft v. Kiskaddon***, 557 Pa. 340, 343 n.1, 733 A.2d 623, 624 n.1 (1999) (citations omitted). "The core issue presented by the demurrer is whether on the facts averred, the

law says with certainty that recovery is impossible. Where doubt exists, this doubt should be resolved in favor of overruling the demurrer." ***Id***.

¶ 19 In the case at hand, count five of Appellants' fifth amended complaint alleged, *inter alia*:

> 60. The TPA therapy which was performed upon William Stalsitz was part of a clinical study involving intra-arterial r-TPA (Recombinant Tissue Plasminogen Activator).
>
> 61. Defendants applied for and received approval from the FDA to participate in the clinical study.
>
> 62. Defendants, as either an approved institution or as a registered investigator were bound by FDA regulations to obtain the informed consent of William Stalsitz.
>
> 63. Defendants assumed a duty pursuant to their FDA application and/or under the laws of this Commonwealth and the regulations governing it to provide to William Stalsitz information sufficient to knowingly decide whether to undergo the procedure(s).
>
> 64. The TPA therapy, angiography and angioplasty performed upon Plaintiff William Stalsitz was instituted as a surgical invasive procedure(s) via angiographic introduction into the left groin arterial vessel of William Stalsitz.
>
> 65. The serious injures and damages suffered by Plaintiff William Stalsitz were the direct and proximate result of the failure of Defendants to inform Plaintiff fully and completely regarding the risks, the alternatives to the TPA procedure the complications of the procedure and the nature of the procedure itself that a reasonable person would consider material in deciding whether or not to undergo treatment and in further performing such procedure without having obtained Mr. Stalsitz' informed consent.
>
> 66. Defendants further performed angioplasty upon William Stalsitz during the course of this study without any informed consent and without informing William Stalsitz of the risks, nature of and alternatives to that procedure.
>
> 67. In the alternative, Defendants failed to inform of the special, unproven nature of the TPA procedure for thrombolysis, unknown outcomes to be encountered therein and the fact of uncertainties associated with the unproven and experimental procedure.

Appellants' fifth amended complaint at 45-46. Thus, Appellants essentially argue that (1) Appellees were bound by FDA regulations to obtain Mr. Stalsitz's informed consent to participate in the TPA study, and/or (2) Appellees were obligated to obtain Mr. Stalsitz's informed consent because the TPA therapy, angiography and angioplasty performed on him constituted surgical procedures requiring informed consent. In the context of these allegations, Appellants describe Appellee doctors as the agents, servants and/or employees of LVH.

¶ 20 We first address the allegation that Appellees were bound by FDA regulations to obtain informed consent for those procedures performed as part of the TPA study. Before reaching the merits of the issue, we turn our attention to Appellees' claims that the issue, contained in count five of Appellants' third to fifth amended complaints, constitutes a new cause of action that is barred by the statute of limitations.

¶ 21 In general, amendments to pleadings are liberally allowed. But,

> [a]n amendment introducing a new cause of action will not be permitted after the Statute of Limitations has run in favor of a defendant . . . However, if the proposed amendment does not change the cause of action but merely amplifies that which has already been averred, it should be allowed even though the Statute of Limitations has already run.
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> ***Schaffer v. Larzelere***, 410 Pa. 402, 407, 189 A.2d 267, 270 (1963) (citations omitted).

Laursen v. General Hospital of Monroe County, 494 Pa. 238, 243, 431 A.2d 237, 242 (1981).

¶ 22 Appellants' original complaint and their first two amended complaints raise a claim for lack of informed consent premised only on the general rule that informed consent is required prior to the performance of surgical procedures. Under this theory, Appellants argue that Appellee physicians had a legal duty to disclose the risks of surgical procedures performed on Mr. Stalsitz. ***Valles***, 805 A.2d at 1237. Possibly realizing that their claim may fail because (1) hospitals are generally not obligated to obtain informed consent, and (2) informed consent is not required for non-surgical procedures, Appellant's subsequent amended complaints raised a claim under ***Friter***, alleging that FDA regulations required informed consent. We first note that since ***Friter*** was decided in 1992, Appellants could have raised the claim in their original complaint, which was filed in 1994. Under the ***Friter*** allegation, Appellants argue that both the hospital and the physicians owed a legal duty to disclose the "clinical nature of the procedure and the risks associated with such experimentation." ***Friter***, 607 A.2d at 1114. By the time Appellants filed their third amended complaint, however, the two-year statute of limitations for civil actions set forth in 42 Pa.C.S.A. § 5524 had run.[9] Had the trial court addressed LVH's preliminary objections to the informed consent allegation contained in Appellants' original and first two amended complaints, a demurrer to that allegation would have been properly granted under the general rule that a hospital is not obligated to

[9] The procedures in question occurred in January 1992. Appellants' third

obtain a patient's informed consent. Appellants avoided rulings on Appellees' preliminary objections, however, by immediately filing amended complaints thereto. To allow Appellants to amend their complaint to state a ***Friter*** claim of lack of informed consent would be to allow them to assert a new cause of action after expiration of the statute of limitations.

¶ 23 As we discussed above, a common law allegation of lack of informed consent sounds in battery, whereas a claim that informed consent is required under ***Friter*** implicates federal regulations. We reject Appellants' assertion that the ***Friter*** claim is merely an amplification of their original allegations. The third and subsequent amended complaints introduce new factual allegations regarding the investigational study and the FDA regulations governing such studies. In addition, they assert a new claim of lack of informed consent against the hospital, not just the physicians.[10]

¶ 24 Based on the above, count five of Appellants third and subsequent amended complaints raised a new cause of action by asserting that FDA regulations imposed a duty of informed consent on Appellees. Because the statute of limitations had expired, a demurrer to that count was properly

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amended complaint was filed on July 18, 1994.

[10] Appellants' complaints do not differentiate between the hospital and the physicians, but, as we discussed above, Appellants can only pursue an informed consent action against LVH under ***Friter***, since under the general rule only physicians are obligated to obtain informed consent. ***Valles***, 805 A.2d at 1239. Thus, count five of Appellants' original and first two amended complaints asserted an informed consent claim against the physicians only.

granted, and a new trial was properly denied on this ground post-trial. ***Estate of Witthoeft***, ***supra***.

¶ 25 Having so concluded, we turn to the question whether LVH or the physicians were obligated to obtain Mr. Stalsitz's informed consent for the TPA study under common law principles. As we discussed above, the doctrine of informed consent does not obligate a hospital to obtain a patient's informed consent, therefore, a demurrer to Appellants' informed consent claim against LVH was properly granted a new trial was properly denied on this ground post-trial. ***Valles***, 805 A.2d at 1239. With regard to the informed consent claim against the physicians, we find that the demurrer was properly granted because the TPA therapy, which involved the injection of a drug, was not surgical or operative. ***Morgan***, 550 Pa. at 206-207, 704 A.2d at 619-620.

¶ 26 We are thus left with the question whether informed consent was required for the angiogram and angioplasty. Under the law applicable at the time Mr. Stalsitz underwent the treatment in question, only surgical or operative procedures required informed consent, and only the surgeons performing the procedures were required to obtain that consent. ***Valles***, 805 A.2d at 1239; ***Morgan***, 550 Pa. at 205, 704 A.2d at 619; ***Gentzler*** 660 A.2d at 1382. Therefore, as we explained above, LVH was not obligated to obtain Mr. Stalsitz's informed consent for any procedures, as that duty falls to the physician performing the procedures. Thus the demurrer was

properly granted as to LVH. We also find that the demurrer was properly granted with regard to the physicians' duty to obtain informed consent for the angiogram, since that procedure involved the injection of a dye and will be considered non-surgical. ***Morgan***, 550 Pa. at 206-207, 704 A.2d at 619-620. Additionally, we conclude that the demurrer was properly granted with regard to the claim that Doctors Nicholas and Berger were obligated to obtain informed consent for the angioplasty, since it is undisputed that Dr. Jaffe performed that procedure. ***Valles***, 805 A.2d at 1239; ***Morgan***, 550 Pa. at 205, 704 A.2d at 619; ***Gentzler*** 660 A.2d at 1382.

¶ 27 We are unable to determine if the demurrer was properly granted on the issue of Dr. Jaffe's obligation to obtain informed consent for the angioplasty, however, because we are unable to define the angioplasty as surgical or non-surgical. As expected, the parties offer convergent theories. The trial court cites to ***Morgan*** to support its conclusion that "[a]rteriograms and angioplasty fail to require a 'surgical cut and the use of surgical instruments that gives rise to the need to inform the patient of risks prior to surgery." Trial Court Opinion filed 6/29/01 at 9 (*citing* ***Morgan***, 550 Pa. at 207, 704 A.2d at 621 [sic]). A review of that text provides no specific comment regarding angioplasty, but does reveals the following:

> It is the invasive nature of the surgical or operative procedure involving a surgical cut and the use of surgical instruments that gives rise to the need to inform the patient of the risks prior to surgery. Neither of the procedures performed in the instant appeals were invasive in nature as both involved the injection of

> medication which does not rise to the same level of bodily invasion as surgery.

Morgan, 550 Pa. at 207, 704 A.2d at 620 (citation omitted). Here, there can be no question that a balloon catheter was inserted into the artery in Mr. Stalsitz's leg. Appellees argue that no surgical cut was required for this procedure however, since the "balloon wire used for the angioplasty was inserted into the same sheath that had been inserted earlier to permit TPA infusion and infusion of the dye for angiograms." Brief for Appellees Hospital and Jaffe at 35. Our review of the testimony cited by Appellees does not clearly support this claim, however, and regardless, such information would not have been before the trial court when it ruled on the demurrer. In contrast, Appellants point to various medical dictionary definitions, which seem to place angioplasty in the surgical category. The testimony of their own expert witness, however, appears to indicate that angioplasty is considered a non-surgical therapy. N.T. 3/23/00 at 1357, 1359-1360, 1362.

¶ 28 As we noted above, in reviewing a trial court's decision to grant a demurrer, all material facts set forth in the complaint and all inferences reasonably deducible therefrom are accepted as true, and the core issue is whether on the facts averred, the law says with certainty that recovery is impossible. ***Estate of Witthoeft***, 557 Pa. at 343 n.1, 733 A.2d at 624 n.1. Any doubt should be resolved in favor of overruling the demurrer. ***Id***. Since we are unable to determine that the angioplasty was non-surgical, however, we simply cannot reach the conclusion that the law says with certainty that

recovery is impossible with regard to the claim that Dr. Jaffe was obligated to obtain informed consent for the procedure.

¶ 29 Even if we were to assume that the demurrer was improperly granted with regard to Dr. Jaffe's failure to obtain informed consent for the angioplasty, however, we do not find that Appellants are entitled to a new trial on this basis, as they cannot show they were prejudiced. As we noted above, the jury found that Dr. Jaffe breached the standard of care, even without reaching the question of whether he should have obtained informed consent for the angioplasty. Having so concluded, however, they did not find that Dr. Jaffe's conduct was a substantial factor in causing Mr. Stalsitz's harm. Therefore, we conclude that the trial court did not err in denying Appellants' motion for a new trial. ***Petrecca***, ***supra***. For the foregoing reasons, Appellants' first allegation is without merit.

¶ 30 Appellants next assert that the trial court erred in failing to preclude evidence that Mr. Stalsitz was subsequently hospitalized and underwent angiograms, because (1) such evidence was irrelevant and more prejudicial than probative, and (2) such evidence was beyond the scope of the testifying expert witnesses report. This allegation is governed by the Pennsylvania Rules of Evidence and the Pennsylvania Rules of Civil Procedure.[11]

[11] The Pennsylvania Rules of Evidence were adopted on May 8, 1998 and are applicable to proceedings beginning on or after October 1, 1998. The instant

¶ 31 Rule 401 defines "relevant evidence" as that which has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Pa.R.E. 401.[12] Pursuant to Rule of Evidence 402, relevant evidence is generally admissible, and irrelevant evidence is inadmissible. Pa.R.E. 402. Further, relevant evidence may be excluded if its probative value is outweighed by its potential for "unfair prejudice," defined as a "tendency to suggest decision on an improper basis or to diver the jury's attention away from its duty of weighing the evidence impartially." Pa.R.E. 403; Pa.R.E. 403 Comment 1998. Expert witnesses are permitted to testify under Rule of Evidence 702. Pursuant to Rule of Civil Procedure 4003.5(c), "[t]o the extent that the facts known or opinions held by an expert have been developed in discovery proceedings …, the direct testimony of the expert at trial may not be inconsistent with or go beyond the fair scope of the [expert's report]." Pa.R.C.P. 4003.5(c). "However, the expert shall not be prevented from testifying as to facts or opinions on matters on which the expert has not been interrogated in the discovery proceedings." ***Id***.

> The admission of expert testimony is within the trial court's sound discretion and we will not disturb that decision without a

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trial commenced on March 16, 2000, and is, therefore, governed by the Rules.

[12] Rule 401 codified existing law as represented by the Supreme Court's definition of relevance in ***Commonwealth v. Scott***, 480 Pa. 50, 54, 389 A.2d 79, 82 (1978). Pa.R.E. Comment 1998.

> showing of manifest abuse of discretion. An expert's testimony on direct examination is to be limited to the fair scope of the expert's pre-trial report. In applying the fair scope rule, we focus on the word "fair." Departure from the expert's report becomes a concern if the trial testimony "would prevent the adversary from preparing a meaningful response, or which would mislead the adversary as to the nature of the response." Therefore, the opposing party must be prejudiced as a result of the testimony going beyond the fair scope of the expert's report before admission of the testimony is considered reversible error. We will not find error in the admission of testimony that the opposing party had notice of or was not prejudiced by.

Coffey v. Minwax Company, Inc., 764 A.2d 616, 620-621 (Pa. Super. 2000) (*citing* ***Petrasovits v. Kleiner***, 719 A.2d 799, 804 (Pa.Super. 1998)). ***See also Brady v. Ballay, Thornton, Malloney Medical Associates***, 704 A.2d 1076, 1079 (Pa. Super. 1997) ("Admission of expert testimony is a matter within the sound discretion of the trial court and will not be disturbed absent a manifest abuse of discretion. Where, however, it is evident that the trial court has misapplied the law or reached a manifestly unreasonable, biased, or prejudiced result, this court will find the error reversible."). "The purpose of requiring a party to disclose, at his adversary's request, 'the substance of the facts and opinions to which the expert is expected to testify' is to avoid unfair surprise by enabling the adversary to prepare a response to the expert testimony." ***Corrado v. Thomas Jefferson University Hospital***, 790 A.2d 1022, 1029 (Pa. Super. 2001) (*citing* ***Walsh v. Kubiak***, 661 A.2d 416 (Pa. Super. 1995)).

¶ 32 Here, Appellants specifically allege that the trial court erred in allowing evidence that Mr. Stalsitz received additional lytic therapy and angioplasty at

LVH in 1997. We first address whether this evidence should have been precluded as irrelevant and more prejudicial than probative. Again, evidence is relevant if it makes a fact more or less probable than it would be without the evidence. Rule of Evidence 401. Here, Appellants' expert witness testified that an angioplasty of the type performed on Mr. Stalsitz was "not a technique that worked with any type of longevity," that it had only a fifteen percent one year patency rate versus a ninety percent one year patency rate for surgical bypass or surgical treatment, and that it should not have been done based on the potential for a poor outcome. N.T. 3/23/00 at 1359-1360. Appellees countered that they did not breach the standard of care in performing the 1992 angioplasty, and that such treatment was, in fact, appropriate, since Mr. Stalsitz achieved more than five years of patency in his artery following the 1992 angioplasty. We find that evidence of the 1997 lytic therapy and angioplasty on Mr. Stalsitz's leg is relevant in that it supported Appellees' contention that the 1992 angioplasty was an appropriate method of treating the stenosis and did not represent a deviation from the standard of care.

¶ 33 Appellants argue that any relevancy is far outweighed by the prejudice created by the testimony concerning the 1997 treatments. Appellees counter that the admission of the evidence could not have been prejudicial, since the jury did, in fact, find that LVH and Dr. Jaffe breached the standard

of care. We agree. Again, Appellants have failed to convince us that the trial court erred in denying a new trial on this ground.

¶ 34 With regard to whether evidence of the 1997 treatment was beyond the scope of Appellees' expert witness' report, the trial court found that the testimony was "a fair extension of the comments made in [the report]," and "offered no surprises and did not prejudice [Appellants] in any way." Trial Court Opinion filed 6/29/01 at 20. For the reasons stated above, we agree that Appellants were not prejudiced by the admission of the evidence, and, therefore, the trial court did not err in denying a new trial on this ground. ***Petrecca***, ***supra***, ***Coffey***, ***supra***.

¶ 35 Appellants lastly assert that the trial court erred in admitting the testimony of a witness based on documents that, although previously requested by Appellants, were not produced by Appellees until the end of the trial day prior to Appellees calling the witness to testify.

¶ 36 By way of background, part of Appellants' argument at trial was that there was a delay in diagnosing Mr. Stalsitz with compartment syndrome, and that the delay was a substantial factor in causing damage to his leg. Dr. Jaffe testified that he diagnosed the compartment syndrome when Mr. Stalsitz was in radiology for a CAT scan on January 15, 1992. The parties disagreed as to the time the CAT scan was performed, and although the CAT scan film is time and date stamped, Dr. Jafee testified on cross-examination that the CAT scan machine's clock was never accurate. N.T. 3/17/00 at 455.

In response to Appellants' request for records for any CAT scan machine from January 1991 through January 1992, Appellees had only provided records pertaining to a CAT scan machine manufactured by Siemens. In addition, however, Appellees listed Robert Spicer, an employee of G.E., as a potential witness, although Appellants were never provided with records from the G.E. CAT scanner that was actually used on January 15, 1992. Prior to calling Mr. Spicer to testify, Appellees provided Appellants copies of records concerning the G.E. scanner. Appellees had no explanation for why Appellants had not received the records prior to trial. Appellants objected to Mr. Spicer's testimony and the use of the records on the grounds of prejudicial surprise. N.T. 3/29/00 at 2341. Appellants counsel acknowledged, however, that she was aware that Mr. Spicer was a potential witness and that she had attempted to contact him prior to trial. ***Id***. at 2347. The trial court allowed Mr. Spicer to testify on the condition that Appellees could not use the records pertaining to the G.E. scanner in their case in chief. ***Id***. at 2348-2349. The trial court further ruled that if Mr. Spicer was questioned on cross-examination regarding the specific date of January 15, 1992, Appellees could then refresh his recollection using the records. ***Id***. at 2349.

¶ 37 Mr. Spicer subsequently testified on direct examination that he performed weekly maintenance on the G.E. scanner for a period of approximately eleven years, including January 1992. N.T. 3/29/00 at 2359.

Mr. Spicer specifically testified, however, that he had no direct recollection of working on the scanner or looking at its clock on or around January 15, 1992. ***Id***. at 2360. Mr. Spicer was able to confirm, however, that generally, during the course of his work, the clock on the machine was incorrect by several hours, and that the deviation varied from week to week depending on how long the system had been running. ***Id***. at 2359, 2361. Mr. Spicer explained that the clocks on some equipment were just inherently inaccurate and lost time. ***Id***. at 2378. Mr. Spicer further testified that when the machine was re-booted as part of the normal weekly maintenance procedure, it would reset to a default time and date, at which point the operator could then set the correct date and/or time, individually. ***Id***. at 2363-2364, 2367. As Dr. Jaffe testified, however, the technicians did not usually reset the time or date. N.T. 3/17/00 at 455.

¶ 38 On cross-examination, Appellants' counsel asked Mr. Spicer if he had any specific recollection regarding the scanner on any given day in January 1992, to which he responded that he did not. N.T. 3/29/00 at 2364. On re-direct examination and over renewed objection, the trial court allowed Appellees to use the G.E. scanner record, based on its prior ruling that the record could be used to refresh Mr. Spicer's recollection if Appellants questioned him regarding whether he recalled January 15, 1992. ***Id***. at 2371. Appellants then engaged in re-cross-examination of Mr. Spicer. In

addition, Appellants took the testimony of LVH's director of risk management regarding the failure to produce the G.E. records. ***Id***. at 2351.

¶ 39 Based on the above, we conclude that the trial court properly denied Appellants' request for a new trial in this regard. Mr. Spicer was properly identified as a witness, which Appellants' counsel freely acknowledged, the records were not used in Appellees' case in chief, but only on rebuttal, and Appellants were given the opportunity to elicit testimony regarding the production of those records. We discern no prejudice to Appellants requiring a new trial. ***Petrecca***, ***supra***

¶ 40 For the foregoing reason, we affirm the entry of judgment in favor of Appellees.

¶ 41 Affirmed.