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Medical Malpractice, Defective Product/Technology and their Rules of Engagement – Is it time to re-think?

George Gregory Buttigieg*

Faculty of Medicine and Surgery, University of Malta, Hungary

***Corresponding author:** George Gregory Buttigieg, Senior Lecturer, Faculty of Medicine and Surgery, University of Malta, Hungary, Tel: +356 2340 1102; E-mail: george.g.buttigieg@um.edu.mt

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Abstract

The article reviews some aspects of medico-legal jurisprudence involving adverse effects related to the use of bio-medical products and medical technology. It looks at crucial points of interaction and puts forwards damage limitation suggestions involving both the medical as well as the legal fronts. While evaluating the rapid and intrepid use of ever more intricate technology, the author draws attention to the increasing complexity of medical technology playing major roles in diagnosis and treatment, increasing the window of potential malpractice and liability. Briefly reviewing historical and current Court attitudes in general, the article emphasizes the urgent need to pause, reflect and modify as needed by the changes of current practice and its projected future.

The author also quotes the 2015 critically important UK Supreme Court ruling in Montgomery v Lanarkshire Health Board [2015] both for its relevance in the general arguments levied here, as well as for the opportunity it provides for reviewing the worrying aspects of medic-legal jurisprudence analyzed here.

While, by no means condemning the rapid advances of medical technology, the author strongly stresses that it is time to re-think the basic rules of clinical application of medical technology as well as the complex inter-play at medico-legal jurisprudence level.

Keywords: Medical technology; Medical products; Medico-legal; Jurisprudence; Bolam test; Pre-emptive

A Time to Pause and Reflect

The world of medical technology, by its very nature, can have neither evolutionary rest nor developmental limitation. In fact its breath-taking progress may out-strip time consuming reflection on its optimal use to strike the ideal risk/benefit balance all round, including the practitioner's medico-legal protection [1-3]. There are situations where ethical limitations morph into legal enforcement such as is the case limiting the number of fertilized ova to be inserted inside a uterus in IVF technology. More often than not, the practitioner's involvement with technology, however advanced, is limited to technical mastery and little reflection of resulting potential legal involvement. The exciting prospect of obtaining new and previously unavailable, positive results through enhanced technology is a heady motive to move forward and practice. Rarely, the new techniques are taught through short courses, organized by manufacturing giants. Applying in vivo often shortly follows rapidly after. This may also be followed by a period of long repenting at leisure [4-7].

The scope of this paper is not only not to condemn medical technology but rather to draw attention to the urgent need of pre-emption in diminishing medico-legal disputes involving such technology at all levels. And if we are talking medico-legal jurisprudence, we also need to pause and reflect on the stance, we, as clinical practitioners, must take, at the moment of evaluating and use new products and techniques [8]. Much is, often made of unfair and parasitic medico-legal battles. However, if we look, for example at the world of the heavily sued OBGYN, it is worthwhile remembering that about 75% of medico-legal cases do actually, involve sub-standard practice. 75% of cases do not involve parasitism but a fair and justified plea for legal rectification of a job not well done, for whatever reason [9-10].

Hence it is up to us, medical practitioners from whichever discipline, to clean our house. On this occasion, I make special reference to the super-fast evolving aspect of medical care involving new medical products and new biotechnology [11]. I will here omit reference to those "forces" with major interest in fostering litigation. My concern in this instance lies with the evaluation of genuine medical liability in the presence of a final adverse outcome. Simple reflection shows that we speak of no small number, whether we consider the regular and routine use of medical products or technologically oriented medical practice or whether we consider alleged liability involving such technologically oriented practice [12].

Across the Board

The use of bio-medical products and technology essentially covers almost all medical disciplines. If we look at OBGYN again, ever increasingly complex laparoscopic surgery, the use of mesh oriented pelvic surgery, a multitude of IVF oriented techniques, speak for themselves. All aspects of general and specialized surgery have experienced varying degrees of enrichment through newly bio-engineered products be it in minimally invasive techniques, transplant surgery, cardio-thoracic practice, orthopedic replacement procedures. Interventional radiology and diagnostic imaging have gone through a major volte face. Anesthesiology, dentistry, ophthalmology are all

littered with new products ranging from new infusion pumps to laser, computer network system integration [13,14].

We hardly reflect on the tortuously difficulty of establishing the legally oriented Standard of Practice for legal cases involving a medical product and/or medical equipment technology used in clinical practice. Once the medical product/equipment is in clinical use, establishing liability in the unfortunate case of an adverse outcome may involve complex reasoning which can challenge the best minds in the subject. The Courts, with ever expressed equanimity, may find their best medico-legal exponents face ever increasing challenges of discernment before passing judgment.

I will take one small pointer as an index of the broadness and extent of reported problems arising with products from the world of bio-technology. In one day, namely the 24 March 2017, 13 notices of warnings about some aspect or another of medical product/technology were issued and distributed to all Maltese local hospitals, clinics and laboratories. The products include 3 Internal orthopedic fixation systems, an antigen Lateral Flow Assay, a hematological cell analyzer, a patient monitoring system central station monitor, a digital stationary angiographic x-ray system, a surgical torque wrench, a cardiac catheterization laboratory computer, 2 medical device insertion instruments, an endoscope, and a liquid ring system. This is by no means atypical reportage of such warnings/withdrawal of products is based on the obligatory reporting of product malfunction or complications to the MCCAAA under the Product Safety Act V of 2001, as amended by Legal Notice 426 of 2007; and Acts XXIX and of 2007 and VI of 2011 of the Laws of Malta. In one day, we have warnings about potential medical/laboratory/surgical adverse outcomes involving orthopaedics, microbiology, haematology, anaesthesiology, cardiology general, internal medicine, general surgery and dermatology. Here, I am referring to officially issued warnings in Malta, a small southern European island with a population of 429,000 local inhabitants and a European level medical system. One is more than justified on reflecting as to what the total European/ USA reportage per day is like?

Product Liability or Medical Malpractice?

One current example of a product with much medico-legal rancour is the use of meshes applied by gynecologists to treat utero-vaginal prolapse and female urinary stress incontinence. These meshes may be applied abdominally or vaginally, and the immediate post-operative results especially in treating stress incontinence. Immediately post-operatively results may be immediately super impressive – as indeed can longer term complications, including mesh erosion, mesh migration into bladder/bowel or through the vagina, pain, infection, bleeding, dyspareunia, and urinary problems? These may or may not require additional and secondary surgical corrections.

The question asked by this sub-section is currently challenging many legal minds: transvaginal mesh which has been used in hospitals for the last 15 years has currently 60,000 law suits in the US and many thousands more in other countries. With over 400 cases lodged in the Court of Session, Scotland is now facing the largest medical negligence case in legal history. These figures clearly speak for themselves.

It is a question, which further on in the evolution of "vaginal mesh jurisprudence" may produce some answers to the increasingly complex issues raised by technology in the production of new material as well as in the execution of new surgery, only made possible by the newest of technology.

The introduction of vaginal, essentially took off significantly in the 1990's. Whereas previously, the gynecologist used the body's own structures to strengthen the pelvis' support, meshes were introduced in a parallel mentality to that of the of surgeon's use of meshes in hernia repairs. Their introduction into the pelvic floor can be through both an abdominal or a pelvic route and once the "fashion" set in, many gynaecologists felt they could not fall behind and although a particular mesh carries its own risks, a number of general complications appeared on the horizon, including Between 2008 and 2010, the number of pelvic mesh complaints tripled over the preceding 3 years, in the USA. In many countries, and not just the UK, the mass of resultant medico-legal complications await liability judgments. Johnson and Johnson, C.R Bard, American Medical Systems, Boston Scientific and Coloplast have all settled massive amounts of money resulting from such complications. Manufacturers still maintain they released these products into the market with claims that they were safe, effective treatments for pelvic organ prolapse and stress urinary incontinence. One must also add many patients have had excellent results from the use of such meshes both in treating pelvic floor prolapse as well as urinary stress incontinence.

In 2008, the Food and Drug Administration warned of potential complications. From January 2008 through December 2010, the FDA received 2874 additional reports of complications associated with surgical mesh devices used in pelvic floor repair and to correct stress incontinence, with 1503 reports associated with the former and 1371 associated with the latter. In 2016, the FDA upped the risk classification from moderate to high risk. In 2011, FDA- Medical Device Advisory Committee, concluded that not only is the safety and risk/benefit of such meshes not well established such meshes but that, depending on the specific vaginal location being repaired, no advantage may be garnered over the traditional repair.

In any specific case being adjudicated in Court, many elements must be considered in evaluating liability as due to inherent product defect versus medical malpractice. Naturally the two elements are not automatically mutually exclusive and may co-exist. It is possible to have an unsafe product being inserted by an incompetent surgeon or indeed by any surgeon in an incompetent way. Points to evaluate favouring the latter aspect include delving in the aspect of training and the learning curve of the surgeon in question. There is an ocean of difference between a gynaecologist sub-specialised in pelvic surgery who has inserted a few hundred meshes and a general gynaecologist who is performing his first insertion. The previous gynaecologist would not be automatically assumed to have respected the recommended rules of the technique but certainly is in a stronger position. These are extreme examples to make the point about the aspect of liability resulting from incompetent surgery. Here, one needs to stress the critical importance of the operation notes which should be legible, dated and timed and contain as much detail as possible to back up the claim of the correct procedure being followed. The presence or absence of per-operative and immediate post-operative complications, their management and the recorded details all shed their own light. These are but a few points of the myriad which may weigh in favour of medical malpractice in contrast to inherent product defect.

However, even if the element of surgical technical malpractice is completely laid to rest, this does not automatically exculpate the surgeon. If we assume that the mesh is inherently defective, medical liability may still be incurred through the aspect of divulging of pre-operative information to the patient. And this itself will be reflected upon by many factors. One such is whether the operation was

performed before or after 2008 and even more significantly before or after 2016, both dates reflecting the FDA warnings. Furthermore, the element of divulging of all pre-operative information is gaining ever increasingly serious weighting. In fact, it will be interesting to note in those cases awaiting adjudication, especially after the 2015 UK Supreme ruling in in Montgomery v Lanarkshire Health Board, (discussed below), if the final Court verdict is weighted in favour of malpractice, as based on absent or insufficient pre-operative information divulged to the patient. Incidentally, in surgical units using one type of consent form for all gynaecological operations, it is time to consider otherwise. Those whose eyebrows are rising at the frustration of suggestive further paper work, should carefully ruminate on the next section.

Evolving Medical Jurisprudence

It behoves all of us to keep in mind that while technology is evolving and enhancing medical practice, so may evolution of medico-legal principles of jurisprudence match on to deal with adverse clinical results. Not pari passu or anywhere near that. In fact, one of the points of this paper exhorts is further medico-legal evolution embracing scientific product/technology involvement in alleged malpractice.

I will quote here, one concrete example of clear and audible legal evolution which has and will have resounding effects on decisions made by a Court ruling on alleged liability. In 2015, the UK Supreme Court overturned the decision of the lower Courts in the case of Montgomery v Lanarkshire Health Board. Nadine Montgomery had been denied information to enable her to decide on the mode of delivery of her pregnancy. A vaginal delivery rather than a Caesarean Section was advised by her OBGYN specialist, who failed to discuss the substantial risks involved, especially since Mrs Montgomery was a diabetic, of short stature and carrying a large infant. Shoulder dystocia and resulting Cerebral Palsy ensued. Space limitation here eliminates the valuable due discussion of this case, but the UK Supreme Court ruled that the patient should have had this information, no matter how strongly the specialist felt that such information would scare anyone into a Caesarean Section. Doctor does not know best with regard to what information he divulges to the patient regarding any planned procedures.

The UK Supreme Court effectively over-turned the third application (regarding information divulging) of the time honoured Bolam test which had reigned unchallenged since 1957. Bolam was considered to have served its purpose and it is more than likely that those parts of it dealing with diagnosis and treatment will also eventually be successfully challenged in the wake of the Montgomery ruling. Such a change has been deemed overdue with many advantages or potential advantages as one example, even prima facie, the Montgomery ruling would contribute in solving medico-legal dilemmas such as that encountered in applying the Bolam test to the quandary of peer practice vs. evidence based medicine.

Bearing in mind such contemporary evidence of change in medico-legal jurisprudential principles, the ever increasing importance of full and detailed pre-operative divulging of information sheds new light on some aspects of this paper.

Where technology is being used, especially new technology, however routine it becomes, it is no longer the doctor's prerogative to shield or protect or for any reason keep back from the patient, all available information pertinent to case at hand. And this naturally implies that the doctor must familiarise himself with all and the latest information e.g. the 2008 and 2016 FDA warnings.

Perhaps one may add a piece of advice to the eager beaver young surgeon, keen not to fall behind peer practice: it is time, not manufacturer's information, which is the best assessor of outcome where new products/technology hit the market. The epidemic of using the mesh in pelvic floor operations and stress incontinence was promised to herald a new phase of gynaecological achievements. Two decades later – the problem is of such magnitude, that there are now lawyers offering free case review in this area [15].

A Person of Ordinary Care and Skill

Medico-legal litigation will not only ever go away, but it will adapt, evolve hand in hand with the march of medicine and surgery embracing all clinical bio-mechanical aspects. However complex, sophisticated, mechanised, and computerised such aspects are, for at the end of the day the aim is not complexity of treatment but a happy patient with a successful outcome [16].

Basic human shortcomings will apply to all medical practice. These include failure to diagnose or treat properly, poor technique, poor documentation, failure of communication, errors in administration, failure to follow safety procedures and failure of adequate concern. Various accentuations and combinations may lead to failure to practice "secundum artem", leading to legal confrontation. Establishing the particular "artem" is what one crux of the progress of science may entail, for it is on such that one aspect of establishing the golden Standard of Practice may rest.

At Court level, the basic reasoning is the establishment of the Standard of Care' for any particular case awaiting judgement. This is the Court's remit and traditionally has been considered as the standard of care practised by:

(a)a person of ordinary prudence;

(b)a person of ordinary care and skill;

(c)engaged in the type of activity in which the defendant was engaged.

The basis of the reasoning is the already mentioned Bolam Test, where McNair J held his famous enunciation that there is no breach of standard of care if a responsible body of similar professionals supports the practice judged even if this did not comply with the established standard of care [17].

In other words, the norm will not be of a super doctor but an average, prudent one with average and safe skills. This principle still stands and has not been challenged in the way that Bolam's application to the divulging of information in Montgomery.

Much criticism has been levelled at the Bolam test, in spite of which, it has stood solid since 1957. Within the present argumentation, I will stress one point, namely the potential challenge of finding a responsible body of similar professionals to establish what is the average safe practice in use. This may not be an easy matter in these days of sub-specialization and super sub-specialization, even more if compounded by issues involving complex bio-engineered products; limited to the few and those few may in fact be using different products from different parent company manufacturers than those awaiting Court opinion and judgement [18].

We are living in a world where through instant dissemination of information, adverse effects make their presence felt and demand legal recompense before the dust has even settled on the first batch of such interventions, let alone their proper statistically based clinical evaluation [19]. Even more so, even before he dust has hardly settled from the first wave of new operations before others take to the field of action possibly with newer modifications. Like life in general, medicine and surgery, is somewhat replication the mad rush of daily life – destination, at times, unknown.

Down Memory Lane of in Bio-mechanics and its by Paths

The encounter between medicine, law and technology and its legal aftermath are, by no means, a 21st century phenomenon but it has accelerated, potentially beyond what is wise, over the last forty years or so. By memory lane, here one refers to these last decades and not centuries past. There have been both ultra - complex Court cases and others where reasoning was simple, clear, and to the point at least for whoever made the ruling.

It is probably fair to state that where medical devices and equipment are involved the Courts generally seem reluctant to find liability without a clear showing of negligence, be this the doctor's, the hospitals,' the manufacturer's or in combined permutations. Another general observation is that often one body seems to bear the liability. In Gunning v National Maternity Hospital and others we find a case where a laparoscopy had to be converted to laparotomy because a portion of a forceps broke and lodged in the Plaintiff's abdomen. Although here we find the hospital as the main defendant, it could have been the surgeon himself.

Under the theory of strict liability, the seller is held strictly liable for any unreasonably dangerous products which he places on the market. In Magrine v. Krasnica, the court distanced medical practitioners from liability and in Silverhart v. Mount Zion Hospital it also distances the hospital itself in that "In sum, the hospital itself was a user of the needle since such needle was supplied to the hospital for its use in performing medical services incident to the normal and ordinary business of the hospital. The Court of Appeals concluded with clear logic that the process of manufacturing and distribution ended with the person or firm that sold, leased or otherwise supplied the defective needle to defendant.

However, even with the 1960-1970's reasoning, there were no hard and fast rules. An instrument which requires maintenance may have left the manufacturers in pristine condition and not been given the necessary maintenance by the responsible hospital staff. Where does hospital liability commence? And, when instruments malfunction, eliciting unplanned operation modifications, especially if not covered by the original consent, what jurisprudential principles should come into operation? The multi-factorial answer should definitely include special attention to rulings such as Montgomery's which is consonant with the ever increasing right of the individual. Can such principles be aided by further medical pre-emptive action? Should the patient be made aware pre- operatively of specific potential instrumental malfunction or outright failure, at a time when, being under anaesthesia, permission may not be sought for emergency deviations of the planned surgery? These and a myriad other questions are but the tip of the iceberg in a world of bio-medically created products which are in everyday use ranging from stents to defribillators, from implants (themselves ranging widely e.g. from orthopaedic use to HRT implants) to intra-uterine hormone secreting contraceptive devices, from complex laser shooting machines to nanometrically based technology.

Incidentally, on the other side of the coin, one should point out that we also find examples of unfair "blaming one's tools" being was used in trying to blur the medical malpractice /technological interface. In Skidmore v Dartford and Gravesham NHS Trust we find instrumental failure being unjustifiably blamed on a planned laparoscopic cholecystectomy converted to laparotomy, when the patient's left iliac artery was punctured by a trochar. However, this is not your typical medical instrumentation oriented, liability case.

As bio-engineering churns out new and complex equipment involving multiple scientific principles, full understanding of the operation, malfunction, de-and re-assembly responsibilities may involve new and complex legal challenges. For example, computer metadata may result in hospitals and surgeons shouldering more of the liability for robotic surgical misadventures. This is a far cry from the often reassuring stance (reassuring to the surgeon) that the hospital is often held liable for less obvious defects, particularly where there is a duty to inspect and maintain the equipment. This trend involving robotics liability may become stronger, depending on the technology in use and the demands/directives in understanding and mastering its applied scientific concepts and their adjustments for specific clinical application. It is more than likely that clean and clearly defined allotment of responsibility of medical liability between manufacturer, distributor, hospital and practitioner may become more challenging in the future. The "press button A" mentality is commoner than one supposes and is more than likely to lead to unpleasant legal encounters. We must also bear in mind that even in the face of statistically rising medico-legal litigation, many mishaps, some serious and involving product malfunction and/or clear medical malpractice never surface or are quashed before making a statistical dent.

One can wait for medico-legal "precedents" to learn from case law or one may seriously consider systematic, medico-legally oriented pre-emption, involving medical, legal, ethical and technological luminaries. Common sense dictates that it is one or other but an intelligent admixture, which will not wait for precedents but certainly be enriched by them, when, unfortunately they do occur [20].

Time to Reflect, Assimilate and Re-think

It has been argued that evidence-based practice could be used to develop a framework that ensures consistent access to services and quality of care across the country, an approach espoused by the Department of Health. Even so, in the rapidly changing world of evolving bio-medical engineering, genuine evidence -based practice may not have time, opportunity and exposure to fulfill its very required criteria. The situation is such that informed jurisprudential discretion must lie at the heart of Court, and failing the essential criterion of 'being informed', wrong interpretation of the true facts may allot unfair weighting to Court legal argumentation. Jurisprudential discretion, requires not only inate wisdom and an unquestioned knowledge of the law but also expertly informed opinions, ideally matured on the nature at hand and thus armed, the Court is likely to rule fairly in a world of savagely and fiercely competing interests. It is for representatives of all stake-holders to stop, re-think and adjust where possible and make available to Court the "mature" opinions it has evolved after arduous and collective input. Such re-thinking commences by a universal

admission that traditional medicine and medico-legal jurisprudence must take new cognizance of the new bio-technological challenges.

The time has also been made ideal by the window of opportunity created by the UK Supreme Court in Montgomery after unchallengingly accepting McNair J's ruling in the 1957 case of Bolam v Friern Hospital Management Committee. The climate is right, the time opportune. The need is certainly there – one example is the story of the gynaecological use of the mesh. The eager doctor or surgeon, engrossed in his new bio-technological prowess and its results, is likely to be the last person to lend his ears to what is being proposed. That is, until his well - intentioned prowess faces the cold light of the Courtroom. It is then that the nightmare challenge to himself, his practice, his life and his family's well- being suddenly hang in the balance. The problem cannot await individual lessons learnt by case law, although this is certainly one source contributing to pre-emptive action, along with due evaluations of signed consent forms, divulging of information to patients, adequate periodic training, assessment, and certification. From the legal angle, the crucial criteria of Standard of Care, always a Court prerogative would benefit in being challenged by legal brains by applying it to the new, ever changing scenarios related to medical technology in its very vastly changing form. The very grave dissonance between traditional medico-legal reasoning vis-a-vis the meteoric progress of medical technology needs to be heard and acted upon.

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