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FEATURE

VAGINAL MESH IMPLANTS

Vaginal mesh implants: putting the relations between UK doctors and industry in plain sight

Despite government guidance, it remains difficult to unpick industry funding of clinicians in the UK—and specialists in vaginal mesh treatment are no exception. **Jonathan Gornall** reports on the NHS surgeons, professional bodies, royal colleges, and medical conferences that benefit from corporate funding and how this financial involvement is hidden from patients

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The associations of individual surgeons and professional bodies with device manufacturers have done little to assuage the concerns of anti-mesh campaigners that sections of the medical profession are biased towards the technology. They argue that conflict of interest played a part in the rapid adoption of mesh for the treatment of stress urinary incontinence and pelvic organ prolapse.

Research funding by industry is a fact of modern medical life and, despite evidence that it can create unconscious bias affecting results, not in itself evidence of any kind of corruption. But, in the absence of any UK or European equivalent to the US Physician Payments Sunshine Act,[1] which puts all relations between doctors and industry in plain sight, these (often hidden) competing interests undermine public confidence in the healthcare system.

Kath Sansom, founder of the patient group Sling the Mesh, has diligently unearthed connections between UK doctors and companies through a series of freedom of information requests and has a list of surgeons and units that have accepted industry funding in one form or another. "A lot of these individuals were on the original [guidelines] panels looking into mesh implants," she says. "A lot were flown out to America to fancy hotels to have their training in mesh implants and given research grants and sponsorship. This creates the disturbing impression that a surgeon's judgment might be clouded and that the treatment patients are getting might not be based 100% on a conviction that this is the best treatment in terms of safety and efficacy."

Most journals require that authors' conflicts of interest are clearly stated, but campaigners for more transparency say this information is a closed book to the average patient, who has no way of knowing whether their surgeon is involved with a company whose product they are proposing to implant.

On the other hand, as one clinician said on condition of anonymity, if doctors can be accused of conflicts of interest for accepting industry funding, could the same not be said of campaigners who are suing the NHS and manufacturers and hoping to be awarded large sums in compensation?

Industry funded research

The tension-free vaginal tape (TVT) procedure seems to have got off on the wrong foot because of a deal between its inventor, Ulf Ulmsten, and device manufacturer Ethicon.[2] And its reputation was not enhanced by the fact that Ethicon funded the first trial of the procedure in the UK.

The UK and Ireland TVT Trial Group's first paper, published in *The BMJ* in July 2002, found that "surgery with tension-free vaginal tape is associated with more operative complications than colposuspension, but colposuspension is associated with more postoperative complications and longer recovery." Vaginal tape, the authors concluded, "shows promise for the treatment of urodynamic stress incontinence because of minimal access and rapid recovery times." Cure rates at six months "were comparable with colposuspension."[3]

A two year follow-up paper was published in 2004 (concluding that TVT "appears to be as effective as colposuspension" for urodynamic stress incontinence), and a third paper, based on five years of follow-up of 98 patients who had had TVT and 79 who had had colposuspension, followed in 2008. It too reported no significant difference between TVT and colposuspension for the cure of incontinence and noted that "the effect of both procedures on cure of incontinence and improvement in quality of life is maintained in the long term."[4]

Industry funded doctors

Details of competing interests were recorded on all three papers. Karen Ward of Liverpool Women's Hospital's gynaecology department, who coordinated the trial, "was supported by a grant from Ethicon Ltd who also provided materials and additional support to collaborating centres" and both Ward and Paul Hilton had been "reimbursed by Ethicon Ltd for conference expenses

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where this, and related work has been presented." The 2004 paper noted that "funding for the trial was provided by Ethicon Ltd" and the acknowledgments on the papers thanked Ethicon's "monitoring staff."

Hilton, who retired as a consultant urogynaecologist three years ago, told *The BMJ* that the trial "was planned in 1997-98 and was undertaken to the highest standards of research governance at the time." In the '90s, he said, "funding for surgical research from medical research councils was virtually non-existent. Had we not had commercial funding the trial almost certainly would not have been undertaken at all.

"Readers of our papers, and the subsequent reviews that have included its outcomes, must of course be aware of the trial funding and declared interests; the credibility of the work, however, lies in the quality and transparency of the protocol and trial reports. But, would I seek commercial funding for medical research myself, two decades on? Never."

But the medical profession's financial involvement with mesh manufacturers cannot be dismissed as historical. Harder to explain to aggrieved patients is why some researchers and professional bodies accept financial support from industry while others do not.

In September 2017 a joint meeting of the European Urology Association and the European Urogynaecological Association published a consensus statement on the use of implanted materials to treat pelvic organ prolapse and stress urinary incontinence. Of the 24 coauthors of the paper, 17 declared financial relations of some sort—as consultants, speakers, researchers, etc—with a total of 34 companies. All three UK coauthors declared links with industry: two with five companies and the other with six.

Discovering the precise nature of these involvements, and their financial value, is no easy task for members of the public, despite NHS guidelines on the management of conflicts of interest that came into force in June 2017. Designed to increase transparency and bolster public confidence that health service money is being well spent, the guidelines require all NHS trusts to publish a public annual register of interests on their websites. The guidance applies to all "decision making staff," clinical or administrative, and a spokesperson for NHS England told *The BMJ* that this specifically included clinical staff who had the power to enter into contracts on behalf of their organisation or who are involved in making decisions about the commissioning of medicines and medical devices.[5]

Some trusts, however, seem to be interpreting this definition narrowly to include only non-clinical, board level executives, while others have so far failed to make registers publicly available online.

Linda Cardozo is a professor of urogynaecology and a consultant gynaecologist at King's College Hospital, London, who in addition to being a coauthor of the 2017 consensus paper is a former president of the European Urogynaecological Association. In June 2014 Cardozo was a cosignatory of a letter sent to members of the Royal College of Obstetricians and Gynaecologists after the "unexpected" decision by the Scottish government to suspend the use of all mesh for treatment of stress incontinence and pelvic organ prolapse, which, said the letter, would "cause alarm to women not only in Scotland but in the rest of the UK."[6]

According to her declaration on the 2017 consensus paper, Cardozo has received money from six drug manufacturers: "Allergan, Astellas, BMR, Pfizer, Pierre-Fabre, and Syner-Med." *The BMJ* has been able independently to establish the value of only three of those associations—from Allergan (a speaker honorarium and consultancy), Astellas (speaker honorarium, consultancy, fellowship, and travel grant), and Syner-Med (consultancy) in 2016, for a total of £20 762 (€23 000; $29 000)—but only after drilling into the transparency declarations of those companies lodged with the Association of the British Pharmaceutical Industry.[7] Even under ABPI's voluntary declaration scheme, which applies only to drug companies and not to device manufacturers, disclosure is hit and miss.

There is no indication that Cardozo has ever received support from a manufacturer of mesh products, but there is no public record of any of her financial relations on the King's College Hospital website. Indeed, contrary to NHS guidance that trusts must maintain public registers of interests on their websites, members of the public must contact the foundation trust office to view the register. If they do, they will find that it is a register of the interests only of "directors and governors."

In April a spokesperson said the trust "has a standards of business policy in place that governs staff conduct in this area," but was "in the process of updating its conflict of interest policy and the register of interests that sits alongside it." A draft policy was in circulation and a full register would be in place within weeks. It was not. On 5 October a spokesperson told *the BMJ* that the policy had not been ratified by the board until July. Guidance and information about it would "shortly be circulated to staff … and a register of interests subsequently published on the trust's website."

Cardozo declined to disclose how much money she had received from industry over the past 10 years, from which companies, and for what purposes. However, she told *The BMJ* that it was "standard practice" for companies developing new drugs or devices "to approach the leaders in the field for their advice and guidance" and, for doctors, "engaging in such a process is part of one's duty." It was not, she said, "in itself a conflict of interest but a reflection of that person's standing within the scientific and medical community." It was "only right that doctors are compensated for the time they spend advising companies and that their travel and accommodation costs are covered as well as any out-of-pocket expenses."

It was, she added, "important that any relations with industry are clearly disclosed where facilities exist to do so—eg, when speaking at conferences or sitting on official committees such as the RCOG." By ensuring that any potential conflicts of interest were disclosed and known to others, "decisions are less likely to be impaired or influenced by a secondary interest. In clinical practice it is important the doctors decide what treatment is appropriate for each patient based on the most up-to-date guidelines and evidence published in peer reviewed literature, and not on any relationship they may have developed with a pharmaceutical company or device manufacturer."

She had, she said, "often gone to companies to ask for support for trainees to present their research at local, national, and international meetings" and "requested sponsorship to put on educational meetings and run courses and to sponsor such activities at the RCOG and the Royal Society of Medicine. Thus the majority of the money that I obtain from industry is not for personal gain but for the greater good of others."

The failure of some trusts to comply with NHS guidelines on the management of conflicts of interest contributes to a lack of clarity that benefits neither patients nor doctors. The UK organiser of the 2017 consensus paper was Chris Chapple, a consultant urological surgeon at Sheffield Teaching Hospitals NHS Foundation Trust. Chapple has published and lectured extensively on the problems caused by the use of mesh and is

working with materials scientists at Sheffield University to develop a polyurethane based alternative.

On the consensus paper he declared five industry associations: "consultant, speaker, and researcher for Allergan, Astellas, Boston Scientific, Medtronic, and Recordati." The value of only one of these associations—the £10 162 he received as a speaker, consultant, and researcher from Astellas in 2016—is publicly available, again through ABPI transparency data. Medtronic and Boston Scientific are both manufacturers of mesh products, but Chapple says his involvement with Medtronic was as a member of its advisory board on sacral neuromodulation and he was "not aware they marketed a vaginal mesh product." He had "never spoken on mesh on their behalf", nor on behalf of Boston Scientific, which had given an unrestricted educational grant to support the consensus meeting between the European Urogynaecology Association and the European Association of Urology, of which Chapple is secretary general. The meeting "was not attended by the company [which] did not see the programme and only saw the report when it was published in *European Urology*."

But none of this is apparent on Sheffield Teaching Hospitals NHS Foundation Trust's website. Back in April a spokesperson said the trust was "in the process of updating its conflict of interest policy and the register of interests that sits alongside it" and a full register would be in place within weeks, but it was not. The policy was not ratified by the board until July, and this week a spokesperson said the trust was "just waiting for the electronic recording system which supports this to be finalised ... We are hoping this will be up and running very soon."

The third UK coauthor of the consensus statement was Mohamed Abdel-Fattah, a consultant urogynaecologist at Aberdeen Maternity Hospital, who declared five industry associations: "past speaker for Bard, Coloplast, AMS, Pfizer, and Astellas; research grant from Coloplast; previous chairman of the Scottish Pelvic [Floor] Network, sponsored by various industrial companies."

Royal colleges and professional groups

As Abdel-Fattah's declaration reminds us, it isn't only individual clinicians who have financial links with industry but professional groups. Although these links are often declared on their websites, they represent a source of influence that patients are unlikely to be aware of. For example, the Ethicon Foundation Fund offers travel grants to fellows and members of the Royal College of Surgeons, the Royal College of Physicians and Surgeons of Glasgow,[9] the Royal College of Surgeons of Edinburgh[10] and the Royal College of Surgeons in Ireland.[11] In its annual report for 2016-17, the Royal College of Surgeons acknowledges "funding partnerships" with 68 companies, including Ethicon, Cook Medical, and Medtronic. In that year donations and grants from all sources, including companies, foundations, individuals, charitable trusts, and endowments, amounted to £5.3m.

The Royal College of Obstetricians and Gynaecologists also offers Ethicon awards to its members. In 2016 three members received "student elective awards" and one senior consultant was given a travel award. Accounts for the year to December 2015 (the most recent that are publicly available) show a contribution of £133 402 from Ethicon.[12] On a section of its website promoting advertising, sponsorship, and exhibition opportunities to companies, the college says there are "a wide variety of ways in which the RCOG can help you connect with our global network of 16,000 Fellows and Members and the wider O&G community." Companies are invited to "portray key messages to a focused, influential audience, leaving a strong and lasting impression of your brand and organisation."[13]

Much of the concern over mesh has centred on the failure of the medical profession to set up an effective register of procedures when mesh was introduced; this could have highlighted long term adverse outcomes before they became widespread. Although the British Society of Urogynaecology (BSUG) did set up a register in the mid-2000s, the fact that this was done with industry support has raised suspicions among anti-mesh campaigners.

The issue was raised by a patient member of the NHS England mesh working group, which included a response from BSUG in its 2015 interim report. "Setting up and running a database of this sort entails significant time and costs which we as a society do not have," said BSUG. The initial costs had been met "by the acceptance of several unrestricted educational grants from a number of companies [including] a number of the companies that manufacture tapes for stress urinary incontinence and mesh for prolapse surgery." The companies "had no say in the way the database was designed or run."[14]

Industry funded conferences

There are three main annual global conferences for urologists and urogynaecologists, and each one is heavily dependent on financial support from industry.

ICS 2018, organised by UK registered charity the International Continence Society, was held in Philadelphia over three days at the end of August. On its website ICS invited industry to "be part of the largest global meeting on continence." Companies were offered the opportunity to "reach key thought leaders … researchers, and clinicians" by exhibiting, organising symposia or otherwise promoting themselves. Among the 23 companies signed up for the exhibition at the Pennsylvania Convention Centre were Medtronic, Boston Scientific, and Coloplast. Of the 3258 worldwide members of ICS, 43% are from Europe and some 112 clinicians from the UK signed up to attend ICS 2018.

The ICS is unusual among professional bodies in that the biographical details of members posted on its site include disclosures. For example,

Paul Abrams, professor of urology at the Bristol Urological Institute, is a former general secretary of the ICS. He declared on 17 February 2018 that he had the following "existing or known future financial relationships or affiliations": speaker honorariums from Pierre Fabre, Coloplast, Sun Pharma, Ferring, Astellas, and Pfizer; consultant work for Ferring, Ipsen, Pfizer, and Astellas; and trial participation with Astellas. Amounts are not given, but the ABPI website shows that in 2016 Astellas and Pfizer paid Abrams a total of £39 946 in fees for "service and consultancy."

Marcus John Drake, a urologist at the Bristol Urological Institute and a trustee of ICS, declared the following financial relations on 19 January 2018: speaker honorariums from Pfizer, Allergan, Ferring, and Astellas; consultancy work and research grants from Ferring and Astellas; and trial participation with Allergan and Astellas. ABPI data reveals Astellas paid him £47 000 in 2016 (less than the £68 897 he received from two companies the previous year) in fees for "service and consultancy."

The International Urogynecological Association, whose annual meeting took place over four days at the end of June, also relies on industry support. Industry sponsors of the meeting in Vienna included Neomedic International, which produces mesh products, and Promedon, which produces mesh products and bulking agents to treat stress incontinence, and mesh devices for pelvic organ prolapse. The two dozen or so exhibitors included Coloplast.

A spokesperson for the association declined to say how much money industry had contributed to its 2018 conference but said that typically about 20-25% of the revenue generated by such meetings came from industry, with the balance coming from "registrations, educational grants, local support, etc." Speakers are required to display slides disclosing industry links at the beginning of presentations, and IUGA publishes an online disclosure report.

The 2018 annual meeting of the European Association of Urology, billed as "Europe's largest urological event," took place in Copenhagen on 16-20 March and was attended by 10 000 urologists from over 100 countries, including the UK. The association offered "numerous benefits" for companies exhibiting at the meeting, including "targeted promotion opportunity, excellent exposure and an outstanding occasion to explore the market." It featured an exhibition with stands from more than 120 companies, including AMI and Coloplast, which make mesh products.

More than observers

The UK Pelvic Floor Society, whose members use synthetic meshes for prolapse and incontinence surgery, is supported by

Shire, Cook Medical, Medtronic, THD, and BK Medical. On its website the society "gratefully acknowledges the indispensable role that healthcare companies play in helping the society to maintain its focus on our ambitious and progressive programmes … as well as unconditional financial support through educational grants to allow for the development and maintenance of our web based database."

The minutes published on the society's website, which was paid for by industry, show that it has a close link with one mesh company. On 20 January 2015, the society's executive meeting in Bristol was attended by two Medtronic representatives—Ruth Hodgkinson, a product manager, and Nick Inman, a market development manager. According to the minutes, Hodgkinson "had worked on an industry sponsorship document for financing" the society. "The emphasis was on industry presence at our three meetings—ACP, two-day annual meeting, and scientific meeting," read the minutes. "Ruth said the real attraction for a company was sponsorship of a symposium at a meeting. Prices from 15k—etc."

The notes suggest that the industry representatives were more than mere observers of the society's business: Hodgkinson "stated that industry wishes [the society] to be a separate entity from other societies … for example, her company (Medtronic & Covidien) would wish to use different sources to fund different activities—eg annual conference funding, immersion courses, small chapter meetings etc." Two consultant colorectal surgeons—Mark Mercer-Jones, current honorary secretary of the society's executive committee, and Andrew Williams, the current chair of the society—were assigned to work on this with Hodgkinson, whose name crops up again in the minutes in a discussion about training. Again, it is Mercer-Jones and Williams who are "to discuss with Ruth formation of immersion courses in LVMR [laparoscopic ventral rectopexy]."[15]

Hodgkinson features in the minutes of a subsequent meeting in London in 2015, when it was recorded that the prospectus for attracting industry sponsorship for a forthcoming meeting in Manchester "would be worked on between Mark Mercer-Jones, Andy Williams and Ruth Hodgkinson." It was also recorded that the two surgeons had met Hodgkinson "to debrief" after running an LVMR training course at Gateshead.[16]

Not all members are comfortable with such close involvement. In an email chain sent to me, apparently in error, in April this year, one member of the Pelvic Floor Society wrote: "I have completely dissociated myself from any personal industry sponsorship now, going to the lengths of turning down a fee from [company name redacted by *The BMJ*] for talking last year. It is just not worth it." The writer added: "We have to be really careful about what is written in minutes that are publicly available."

In 2017 Mercer-Jones and Williams were two of four coauthors of a position statement by the Pelvic Floor Society issued on behalf of the Association of Coloproctology of Great Britain and Ireland on the use of mesh in ventral mesh rectopexy (VMR). The statement, issued "in light of ongoing concerns by the media and public groups surrounding the use of mesh in patients with pelvic organ prolapse (POP) and female stress urinary incontinence (SUI)," advised patients that "VMR … is the best available treatment in the UK to restore normal rectal function."

Of the four authors, three declared conflicts of interest. Charles Knowles, professor of surgery at the National Bowel Research Centre, Queen Mary University London, was "a paid consultant and speaker for Medtronic in relation to sacral neuromodulation," Williams was a "non paid consultant for Cook Medical and Medtronic in relation to pelvic floor surgery and anal fistula surgery," and Mercer-Jones was "a preceptor [instructor] for Medtronic in relation to LVMR."[17]

The subject of the consensus statement had been raised at a meeting of the society at Bristol in January 2013, along with a suggestion that device company Cook Medical was involved . "Global consensus statement on LVMR—[Mercer-Jones] will discuss with Cook in Oxford," the minutes read.[18]

Williams told *The BMJ* there was "no doubt that [the society] is reliant on industry funding. In fact, without it, it would not exist … to encourage full membership there are no fees and so we are reliant on generating our own funding [and] unfortunately this means industry involvement."

The society was, he said, "aware of the potential criticisms levelled at us for engaging with industry" but "the focus for industry financial support has changed over the past five years with companies under much stricter regulation for compliance and a real drive to support education rather than just product placement."

The recent position statement had been "very clear not to bias for any specific type of mesh" and was "a completely non-biased paper with no direction towards the companies that support us the most." The society, he added, had "striven to maintain integrity and independence, despite our reliance on industry funding. I have total confidence in saying that with regard to training, information, and the database we are completely impartial and industry has had, and will never have, any bias on our activity. We are, however, extremely grateful to our industry supporters, without whom none of the achievements of the PFS to date would have been possible."

UK trails in transparency stakes

Regardless of the perceived or actual effect of such extensive industry influence within specialist branches of the medical profession, none of this information is freely or easily available to the public in the UK. The UK trails far behind the US, where since 2013 pharmaceutical and medical device companies have had to publicly record all financial relations with physicians, which can be viewed online through the easily searchable Open Payments portal managed by the Centers for Medicare and Medicaid Services.[1]

The reporting system, legislated in the Sunshine Act, was set up after a series of reports identified extensive conflicts of interest,[19] with one study finding that over 80% of doctors in the US received gifts and 28% accepted payments from industry.[20] A linked analysis of Sunshine Act and Medicare prescribing data published in 2016 found that across the 12 specialties examined "the receipt of payments was associated with greater prescribing costs per patient, and greater proportion of branded medication prescribing," suggesting that financial links between doctors and industry influenced clinical decisions.[21]

In the UK, the recent NHS guidance on conflicts of interest notwithstanding, it is industry that is leading the way on transparency. The ABPI's voluntary Disclosure UK site went live in June 2016, but as yet there is no equivalent window on the activities of the medical device manufacturing community.

Device manufacturers are represented in the UK by the Association of British Healthcare Industries. A spokesperson told *The BMJ* that "the relationship between industry and healthcare professionals has long been an important factor in developing and delivering advancements to patient care" and that "the provision of continuing medical education, attendance

at clinical events and advisory work are all examples of where a payment to an individual or an institution may be appropriate."

But, while it was "imperative that robust mechanisms are in place to ensure transparency and scrutiny around any such payments," and the association's mandatory code of practice required that "all transactions between a company and a healthcare professional are reported to the NHS employer,"[22] it had no plans to follow the voluntary transparency lead of the ABPI. "All payments are known within the NHS and are open to managerial oversight within the organisation," said the spokesperson. In addition, NHS England's conflicts of interest guidance "also requires healthcare professionals to report such transactions, and the system does not allow for opting out." But any such declarations aren't yet generally open to public scrutiny.

Searching the US Open Payments database for details of payments by some of the leading mesh device companies shows what legislation can achieve in terms of transparency as well as the scale of corporate financial outreach to medical professionals in the US. In 2016 Ethicon made 459 "general" payments (anything not related to research) worth a total of £5.08m. Ethicon Endo-Surgery paid out $29.4m in general payments and $1.5m in research. Medtronic paid out $94.2m in 110 000 transactions and invested £5.9m in over 1000 research initiatives. Boston Scientific paid $33.5m in general payments and $15.5m in research. Individual doctors in receipt of these funds are easily identifiable.

Competing interests: I have read and understood BMJ policy on declaration of interests and have no relevant interests to declare.

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