Postmarket surveillance of high-risk medical devices needs transparent, comprehensive and independent registries

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The judgement by Chalmers, the progenitor of the Cochrane Collaboration, that under-reporting of research is scientific misconduct may appear harsh, but there are strong ethical arguments why clinical studies should be reported fully—so that unnecessary duplication of research with risks can be avoided and that insecure results can be replicated. Critical readers should be able to understand the data and assess the validity of any conclusions. The Declaration of Helsinki reminds us (at Article 36) that ‘Researchers … are accountable for the completeness and accuracy of their reports’.1

Requirements for reporting secondary research may be less strong but the methods of any study should still be described in sufficient detail to allow others to reproduce it. That has been reinforced by simulation-specific extensions to the Strengthening the Reporting of Observational Studies in Epidemiology recommendations for reporting observational research3 and by the Consolidated Health Economic Evaluation Reporting Standards guidance on reporting economic evaluations in healthcare.4 Aspects of both statements are relevant to the paper by Cronenwett et al5 in this issue ofBMJ Surgery, Interventions, & Health Technologies.

The authors present the costs of using the Vascular Quality Initiative (VQI), a registry maintained by the Society for Vascular Surgery in the USA, to undertake investigations of medical devices that were mandated by the US Food and Drug Administration (FDA). They compare them against the costs which they estimated would have been incurred if the manufacturers had instead organised their own studies. Actual and predicted costs were evaluated for six premarket investigations or postmarket surveillance studies that monitored high-risk devices used either for endovascular aortic repair (EVAR) or for peripheral angioplasty. The manuscript does not name the particular devices or disclose the requirements specified by the FDA, in part because of sensitivities of the manufacturers, nor does it break down the particular costs that were incurred by the VQI registry. The hypothetical (‘counterfactual’) costs were estimated using a published model6 but only the resulting total sums are reported. These omissions, which were self-imposed by the investigators, mean that readers are asked to take the results on trust. That limits the generalisability of their findings.

Frustrations about incomplete disclosure of data concerning postmarket surveillance of high-risk medical devices extend to the European Union (EU) where achieving transparency is hampered by the delegation of regulatory assessments to notified bodies, which as independent commercial organisations are not bound by EU legislation on freedom of access to information. The new EU Medical Device Regulation that will be implemented from 2021 continues to protect the privacy of information submitted by manufacturers.7 It is ironic that medical audit databases now place the clinical outcomes of individual surgeons in the public domain while data about the individual devices that they have used or implanted may be inaccessible. Until September 2016, specific device identities were not recorded by the VQI8 but now there should be no reticence about open disclosure and comparisons between competing devices or about the costs of maintaining registries.

An important issue in the use of registry data for regulatory purposes is its
which method is more clinically effective—giving better
the context of conducting a study in the USA. The focus
mated over the actual cost, as the ‘return on investment’.
estimated cost, as the ‘cost-
as two percentages, using alternate denominators—the
patients with peripheral arterial disease from alterna-
databases. Comprehensive recruitment might be
attained by stipulating that entering data in a registry is
a condition for institutional reimbursement.

The largest component of the actual costs of the registry
studies was the charge per patient to manufacturers for
access to the VQI data.3 The investigators have stated that
this charge to industry is market driven, based on value
and not relatable to specific costs. It includes payments
to participating centres for entering additional data, and
to the subcontractor responsible for monitoring data.
The counterfactual estimates include overhead costs and
per patient payments to centres. The net costs are given
as two percentages, using alternate denominators—the
difference between actual and estimated cost, over the
estimated cost, as the ‘cost-saving percentage’; and the esti-
ated over the actual cost, as the ‘return on investment’.
Both figures are persuasive but their details are specific to
the context of conducting a study in the USA. The focus
was about saving costs and time, but what matters more is
which method is more clinically effective—giving better
quality, more comprehensive and more reliable data.13

There are increasing pressures on regulators worldwide
to develop systems that can give accelerated access for
patients and physicians to new high-risk medical devices.
Such schemes increase the risks of unexpected compli-
cations, however, so they can be considered only if they
are balanced by more postmarket evidence generation.
The risks that are inherent in conditional approvals (or
coverage with evidence development) should be shared
by patients from all regulatory jurisdictions where a
device will be available. Their data should be pooled
through international collaborations of networks of regis-
tries, to enable the earliest possible detection of any safety
signals.14

The benefits that can accrue from comprehensive
registries are best exemplified by Sweden, which has 120
National Quality Registries integrated within its health-
care system. Data are collected routinely through the
electronic health record and linked with other national
databases. Funding is provided by the Swedish Associa-
tion of Local Authorities and Regions. The Swedishheart
registries on high-risk cardiovascular devices have been
used as the platform to develop randomised registry

trials.15 These may provide more valuable data to regu-

lators more cost efficiently than reported by the VQI
investigators, with capture of real-world experience and
ready access to control populations.

The conclusion of Cronenwett et al—that it is more
effective to collect postmarket data about a high-
risk medical device by using an existing registry run by
a professional association than by initiating an indus-
try-led study—is a welcome confirmation of the wisdom
of current trends, at least if results are fully and promptly
reported. Their study reinforces the need for manufac-
turers of all high-risk devices now to collaborate with
academic bodies to support their registries and ensure
their long-term sustainability.

Contributors AF wrote this himself without assistance.
Funding The authors have not declared a specific grant for this research from any
funding agency in the public, commercial or not-for-profit sectors.
Competing interests None declared.
Patient consent for publication Not required.
Provenance and peer review Commissioned; internally peer reviewed.
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REFERENCES
1 Chalmers I. Underreporting research is scientific misconduct. JAMA 1990;263:1405–8.
2 World Medical Association. Declaration of Helsinki – ethical
principles for medical research involving human subjects, 2018. Available: https://www.wma.net/policies-post/wma-declaration-of-
hesinki-ethical-principles-for-medical-research-involving-human-
subjects/
health care simulation research: extensions to the CONSORT and
4 Huserauer D, Drummond M, Petrou S, et al. Consolidated health
economic evaluation reporting standards (cheers) statement. BMJ
2013;346:f1049.
5 Cronenwett JL, Avila-Tang E, Beck AW, et al. Use of data from the
vascular quality initiative registry to support regulatory decisions
yields a high return-on-investment. BMJ Surgery, Interventions,
& Health Technologies 2020.
burden of United States FDA-mandated post-approval studies for
7 Fraser AG, Butchart EG, Szymaiski P, et al. The need for
transparency of clinical evidence for medical devices in Europe.
8 Mohapatra A, Saadeddin Z, Berties DJ, et al. Nationwide trends in
drug-coated balloon and drug-eluting stent utilization in the
9 International Medical Device Regulators Forum. Registry WG/N33
Final:2016. principles of international system of registries linked to
other data sources and tools. Available: http://www.imdrf.org/docs/
imdrf-final/consultations/imdrf-cons-essential-principles-151124.pdf
An Underused Resource for Medicines Evaluation: Operational
proposals for increasing the use of patient registries in regulatory
outcome assessment after aortic aneurysm repair using Vascular


