Good Afternoon, my name is Charmilie Chandrakumar, and I am a member of the Academic Surgical Collaborative. Thank you for the opportunity to present our research on protocols in plastic surgery. This work rests upon the mantra that “A good protocol is an important element in the primary prevention of poor medical research”. We carried out a systematic review on The use of study registration and protocols in plastic surgery research.
DECLARATIONS

No conflicts of interest to declare

(Nothing established the Research Registry and IJS Protocols)

No funding to declare

No financial interests to declare

Ethical approval not applicable

Prior presentations at SARS, Mammary Fold Academic Day and IDEAL, UK Conferences.
In 1999, Chalmers and Altman suggested Medical journals should consider publishing protocols to aid with the primary prevention of poor medical research (Chalmers and Altman 1999).

- Peer review protects against poor study design
- In the interim, transparency has become fundamental to clinical research
- Protocols provide a transparent declaration of the study methodology, reducing outcome bias

Registration of a study protocol and publication of that protocol are therefore important steps in moving evidence based plastic surgery forward by producing higher quality research.
Additionally, there is now an ethical incentive

In 2013, the World Medical Association announced in the Declaration of Helsinki that All studies with human participants should have a protocol registered in a publicly accessible database before recruitment of the first subject.

This is no longer about clinical trials alone (2008 when it was compulsory for clinical trials to be registered)
1/5 surgical RCTs discontinued early
1/3 remain unpublished at 2 years

Dwan 2013 SR: Strong empirical evidence for the existence of study publication and outcome reporting bias within healthcare research

Positive results are more likely to get published

Not only is unpublished surgical research a waste of money, it is also a wasted learning opportunity and is a risk to patients and their involvement in future research

Protocols allow lessons to be learned from errors made from unpublished trials
Research question was simple

This systematic review assessed the number of studies published in leading journals of plastic surgery that had either published or registered a protocol with any mainstream publicly accessible database.

We examined all research articles involving human participants that were published in the three leading journals of plastic surgery from 1\textsuperscript{st} April 2014 to 31\textsuperscript{st} March 2015

Cochrane methodology, used a protocol, Two researchers screened studies for inclusion and performed data extraction, PRISMA compliant

This review is reported in line with the PRISMA statement. The protocol for this study was registered a priori with http://www.researchregistry.com/ (Unique Identifying Number: reviewregistry12).
We then examined all research to assess whether each study had registered or published a protocol with any mainstream registry database.

For each study, we reviewed each of these databases (with which you will be familiar)

And **pubmed (protocol published?)**

AND **methods** for study protocol numbers

AND **references** for references to protocols
This is the process, showing our selection of the final 595 articles.

Articles not addressed by the Declaration of Helsinki were excluded, and so non-research articles, case reports, and animal or cadaveric studies were not examined.
595 articles were included
Just 4% had a protocol registered
3 studies published a protocol in a journal
We then move on to this graph, where we have arranged the 595 articles by study type. The red shows articles which did not register a protocol, and the blue represents articles that did register or publish a protocol. The most common study design was the cohort studies. The study design that most commonly had a registered protocol was the RCT (n=8 of 24, 33.3% of RCTs).
The most common database to register a protocol was ClinicalTrials.gov (n=17).

Also able to discuss protocol registration on NON-publically accessible databases, and change in protocol registration over time.
We may have **missed studies**: however our hand search was exhaustive

Similarly, we looked at top three journals by IF -- **not necessarily ALL of plastic surgery**, but certainly a good chunk of the upper end of the quality scale

Some articles, we may have **missed a registration** -- this is a possibility however remote.

**LIMITATIONS**

- Potential missed studies
- Excluded journals
- Potential missed registrations
Our research showed poor rates of **registration and publication** among 595 papers that we reviewed.

Why is this important…!

What do we do about it…?!
Most importantly, there is an ethical mandate now to comply with this fundamental Worldwide ethical guidance to register protocols.

Re-affirmed in an RCS position statement.

I opened with the statement that protocols guard against poor quality research.
When we published a protocol, the feedback from peer-review altered the design of the final study: went from safety and efficacy, to six outcome domains for AFG.
Everyone should register a protocol
Everyone should publish a protocol, please!
Journals should not accept submissions prior to registration! Registration improves when it is mandatory for submission
Protocol specific journals exist, but surgical research and plastic surgery are behind
The lead author has recently set up a the first journal for surgical protocols.
“User friendly” registries

*e.g. Research Registry, which takes 2 minutes and is free*

It’s time to take our work seriously
Questions

What’s the point of registering a protocol?
Ethical credibility: it’s part of the Helsinki declaration, the necessary standard for medical research
Methodological transparency: Allows declaration of outcomes a priori to reduce outcome reporting bias
Illustrates where protocol deviation occurred and allows explanations for this to be proposed

What’s the point of publishing a protocol?
Methodological critique: Study design will be peer-reviewed that may lead to improvements
Improved data synthesis from incomplete studies: Published protocols are more easily retrieved and unpublished data can be better sourced for subsequent systematic reviews

Questions
Q: What is your view of case series in plastic surgery and protocols?
A: They need one to specify outcomes a priori to reduce outcome reporting bias. Results need to be complete and transparent.

Q: Did you include the European Trials Registry? (Prof Laurence Boon)
A: Not specifically. This would have been picked up by the WHO meta-registry or our hand search of the methods and references.

Q: What are the legal ramifications of cross-Atlantic collaboration and data sharing? (Not sure where this came from)
A: Cannot provide any legal insight as I’ve not shared clinical data across national borders. However, these barriers should be addressed, as collaboration is important and addressing them sooner rather than later will benefit the field.

Q: How do other specialties do?
A: We don’t know. Surgical RCTs have 18% a priori protocol registration, but we don’t know about observational studies in other fields. An area for future work.