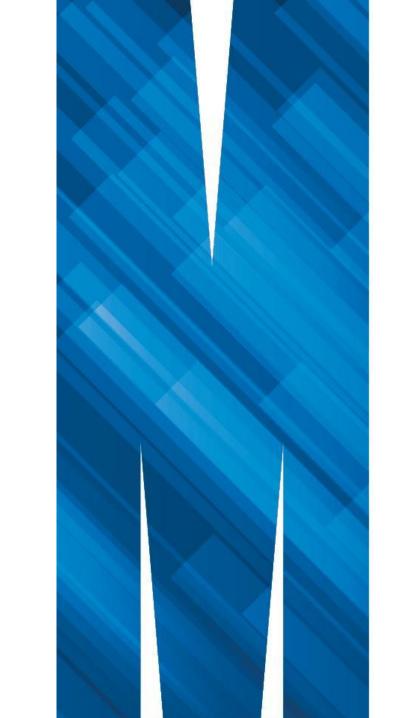


# Post-Publication Response on Concerns raised Regarding False Data in clinical research in Women's Health: A Cohort Study

Siddharth Shivantha BMedSc (Hons), BBiomedSc (Hons) Nicole Au Jim Thornton MD PhD Jeremy Nielsen (Medical Student) Ben W Mol MD, PhD.



#### **Disclosure statement**

- I am a Consultant for Merck, Germany and Organon, USA
- I hold stock for ObsEva
- I am supported by a NHMRC Investigator grant (GNT1176437).
- I have been an invited speaker at sponsored meetings



#### **Health warning**

If you are near to Ben W Mol at a medical conference you are at risk of being killed in the crossfire









Background



Aim



Methods



Results



**Conclusions** 





Contents lists available at ScienceDirect

#### **Pregnancy Hypertension**



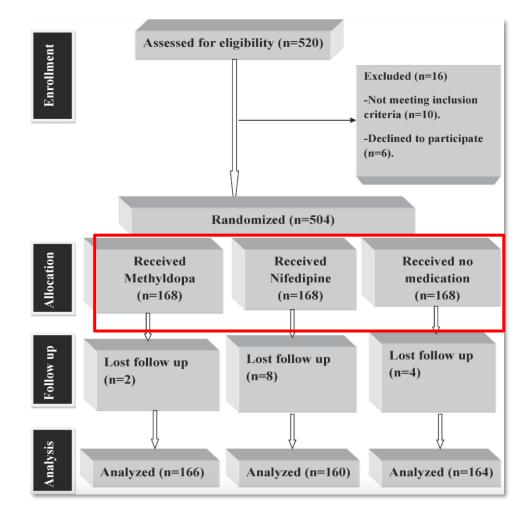


Methyldopa versus nifedipine or no medication for treatment of chronic hypertension during pregnancy: A multicenter randomized clinical trial



Mohamed Salama<sup>a</sup>, Mohamed Rezk<sup>a,\*</sup>, Wael Gaber<sup>a</sup>, Haitham Hamza<sup>a</sup>, Hala Marawan<sup>b</sup>, Awni Gamal<sup>c</sup>, Sameh Abdallah<sup>d</sup>

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Pregnancy Hypertension. Volume 17, July 2019, Pages 54-58





#### **Pregnancy Hypertension**

Volume 19, January 2020, Page 169



#### Letter to the Editor regarding research integrity

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#### Contents lists available at ScienceDirect

#### **Pregnancy Hypertension**



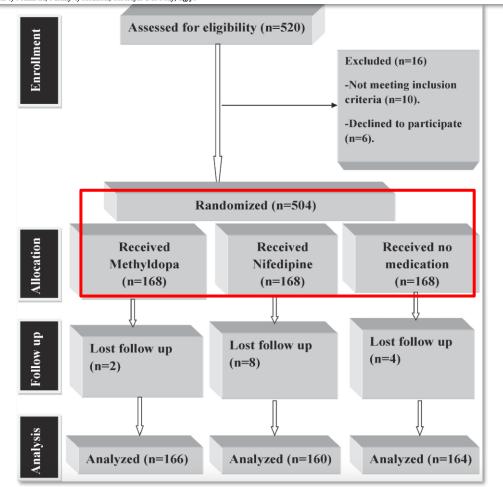


Methyldopa versus nifedipine or no medication for treatment of chronic hypertension during pregnancy: A multicenter randomized clinical trial



Mohamed Salama<sup>a</sup>, Mohamed Rezk<sup>b</sup>, Wael Gaber<sup>a</sup>, Haitham Hamza<sup>a</sup>, Hala Marawan<sup>b</sup>, Awni Gamal<sup>c</sup>, Samen Abdallan<sup>a</sup>

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HYPERTENSION IN PREGNANCY 2020, VOL. 39, NO. 4, 393–398 https://doi.org/10.1080/10641955.2020.1791902





#### Methyldopa versus labetalol or no medication for treatment of mild and moderate chronic hypertension during pregnancy: a randomized clinical trial

Mohamed Rezk<sup>a</sup>, Mohamed Emarh<sup>a</sup>, Alaa Masood<sup>a</sup>, Ragab Dawood<sup>a</sup>, Elsayed El-Shamy<sup>a</sup>, Awni Gamal<sup>b</sup>, and Hassan Badr<sup>c</sup>

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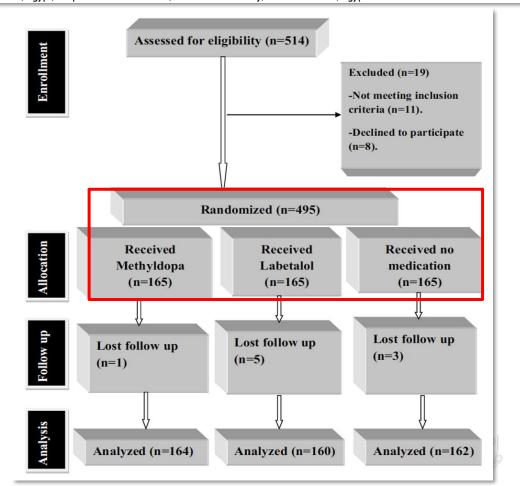






Table 2 Maternal outcome.

	Methyldopa group (n = 166)	Nifedipine group (n = 160)	Control group (n = 164)	Chi square test	P-value	OR at 95% CI
Severe hypertension	38 (22.9%)	36(22.5%)	88 (53.6%)	47.26	< 0.001	0.26 (0.16–0.41)†
Preeclampsia (PE)	44 (26.5%)	46 (28.7%)	80 (48.8%)	22.79	< 0.001	0.25 (0.15–0.41)* 1.02(0.61–1.72)* 0.37(0.23–0.59)* 0.41(0.26–0.66)* 0.89(0.55–1.45)*
Renal impairment	32 (19.3%)	34 (21.3%)	88 (53.6%)	56.67	< 0.001	0.21 (0.13–0.34) <sup>†</sup> 0.23 (0.14–0.38) <sup>*</sup> 0.88 (0.52–1.52) <sup>‡</sup>
Hepatic impairment	36 (21.7%)	38 (23.8%)	48 (29.3%)	2.70	> 0.05	-
ECG changes	36 (21.7%)	40 (25%)	92 (56.1%)	52.45	< 0.001	0.22 (0.13–0.35) <sup>†</sup> 0.26 (0.16–0.42) <sup>*</sup> 0.83 (0.50–1.39) <sup>‡</sup>
Placental abruption	10 (6.02%)	12 (7.5%)	38 (23.2%)	27.55	< 0.001	0.21 (0.10–0.44) <sup>†</sup> 0.27 (0.13–0.54) <sup>*</sup>
Hospital admissions	32 (19.3%)	34 (21.3%)	72 (43.9%)	30.34	< 0.001	0.79 (0.13–0.54) 0.79 (0.33–1.88) <sup>‡</sup> 0.31 (0.19–0.50) <sup>†</sup> 0.34 (0.21–0.56) <sup>*</sup> 0.88 (0.52–1.52) <sup>‡</sup>
Venous thromboembolism	4 (2.4%)	4 (2.5%)	6 (3.7%)	0.57	> 0.05	-
Cesarean Delivery	52 (31.3%)	48 (30%)	58 (35.4%)	1.16	> 0.05	-
Maternal mortality	0	0	0	-	-	-

OR at 95% CI = Odd's ratio at 95% Confidence interval,  $^{\dagger}$  OR between Methyldopa and Control group,  $^{*}$  OR between Nifedipine and Control group,  $^{*}$  OR between Methyldopa and Nifedipine group.

Table 2. Maternal outcome.

	Methyldopa group $(n = 164)$	Labetalol group (n = 160)	Control group $(n = 162)$	Chi square test #	P-value	OR at 95% CI
Severe hypertension	38 (23.2%)	34(21.3%)	86(53.1%)	47.03	< 0.001	0.27(0.17-0.43)*
,,						0.24(0.15-0.39)†
						1.12(0.66-1.89)‡
Preeclampsia (PE)	50 (30.5%)	48 (30%)	78(48.1%)	14.99	< 0.001	0.47(0.30-0.74)*
						0.46(0.29-0.73)†
						1.02(0.64-1.64)‡
Renal impairment	34 (20.7%)	36(22.5%)	88(54.3%)	52.80	< 0.001	0.22(0.14-0.36)*
						0.24(0.15-0.40)†
						0.90(0.53-1.53)‡
Hepatic impairment	40 (24.4%)	38(23.7%)	46(28.4%)	1.40	0.495	
ECG changes	42 (25.6%)	40 (25%)	90(55.5%)	43.22	< 0.001	0.28(0.17-0.44)*
						0.27(0.17-0.43)†
						1.03(0.63-1.70)‡
Placental abruption	10 (6.1%)	12(7.5%)	38(23.5%)	27.87	< 0.001	0.21(0.10-0.44)*
						0.26(0.13-0.53)†
						0.80(0.34-1.91)‡
Hospital admissions	44 (26.8%)	28(17.5%)	76(46.9%)	34.42	< 0.001	0.41(0.26-0.66)*
						0.24(0.14-0.40)†
						1.73(1.01–2.95)‡
Venous	4 (2.4%)	4 (2.5%)	6 (3.7%)	0.59a	0.74	
thromboembolism						
Cesarean Delivery	50(30.5%)	48(30%)	52(32.1%)	0.18	0.912	
Maternal mortality	0	0	0			

OR at 95% CI = Odd's ratio at 95% Confidence interval, \*OR between Methyldopa and control group, †OR between Labetalol and control group, ‡OR between methyldopa and Labetalol group,ª Fischer's exact test. # Yates correction was applied for the Chi-square test.

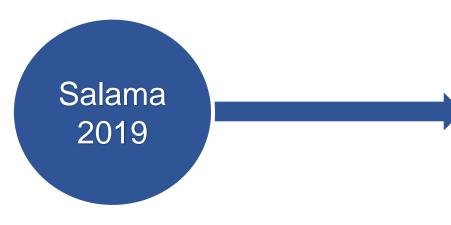




Table 3
Fetal and neonatal outcome.

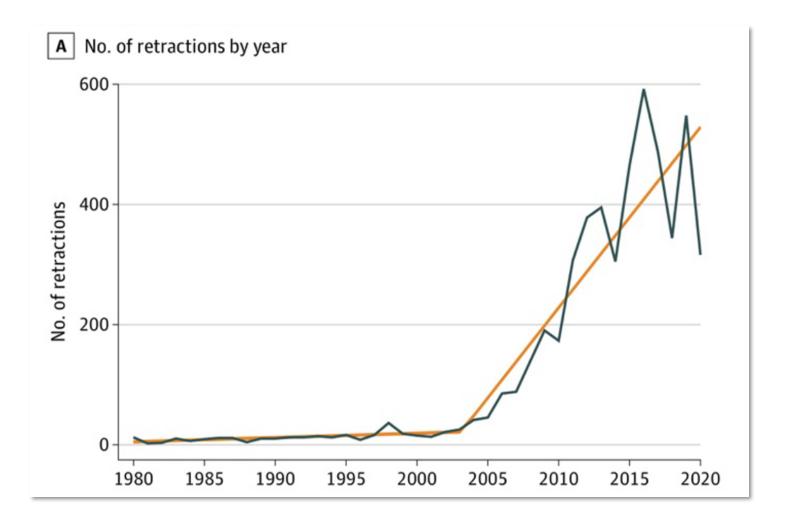
	Methyldopa group ( $n = 166$ )	Nifedipine group ( $n = 160$ )	Control group ( $n = 164$ )	Chi square test	P-value	OR at 95% CI
Small for gestational age	38 (22.9%)	40 (25%)	32 (19.5%)	1.43	> 0.05	_
Intrauterine fetal demise	4 (2.4%)	4 (2.5%)	6 (3.7%)	0.57	> 0.05	-
Prematurity	30 (18.1%)	42 (26.3%)	50 (30.5%)	7.03	0.029	0.50 (0.30-0.84)†
						0.81 (0.50-1.32)*
						0.62 (0.36-1.05)*
Gestational age at delivery (Weeks)	$35.6 \pm 2.62$	$35.42 \pm 2.44$	$35.56 \pm 2.5$	0.89	> 0.05#	-
Birth weight (Kg)	$2.24 \pm 0.62$	$2.26 \pm 0.66$	$2.25 \pm 0.6$	0.56	> 0.05#	-
Apgar score < 7 at 5 min	10(6.02%)	12 (7.5%)	38 (23.2%)	27.55	< 0.001	0.21 (0.10-0.44)†
						0.27 (0.13-0.54)*
						0.79 (0.33-1.88)*
Prematurity	30 (18.1%)	42 (26.3%)	50 (30.5%)	7.03	0.029	0.50 (0.30-0.84)†
•						0.81 (0.50-1.32)*
	_					0.62 (0.36-1.05)*
Admission to NICU	22 (13.3%)	26 (16.3%)	48 (29.3%)	15.12	< 0.001	0.37 (0.21-0.65)†
						0.47 (0.27-0.80)*
						0.79 (0.43-1.46)*
Neonatal mortality	6 (3.6%)	8 (5%)	12 (7.3%)	2.30	> 0.05	_

<sup>\*\*</sup> Student *t*-test, OR at 95% CI = Odd's ratio at 95% Confidence interval, \*OR between Methyldopa and Control group, \*OR between Nifedipine and Control group, \*OR between Methyldopa and Nifedipine group.

Table 3. Fetal and neonatal outcome.

	Methyldopa group	Labetalol group	Control group	Chi square test	Divolue	OD at 050/ CI
	(n = 164)	(n = 160)	(n = 162)	#	P-value	OR at 95% CI
Small for gestational age	34 (20.7%)	66 (41.3%)	32 (19.7%)	23.97	<0.001	1.06(0.62–1.82)* 2.85(1.73–4.70)† 0.37(0.23–0.61)‡
Intrauterine fetal demise	4 (2.4%)	4 (2.5%)	6 (3.7%)	0.59ª	0.74	
Prematurity	30 (18.3%)	42(26.3%)	50 (30.9%)	7.02	0.029	0.50(0.30-0.84)* 0.80(0.49-1.29)†
						0.63(0.37-1.07)‡
Neonatal hypotension	8 (4.9%)	26(16.3%)	4 (2.5%)	24.18a	< 0.001	0.26(0.12-0.60)*
						7.66(2.61–22.51)†
						2.03(0.60–6.86)‡
Neonatal hypoglycemia	6 (3.7%)	8 (5%)	4(2.5%)	1.45a	0.48	
Neonatal	24(14.6%)	52(32.5%)	20 (12.3%)	24.72	< 0.001	1.05(0.55-1.99)*
hyperbilirubinemia						2.94(1.65–5.23)†
						0.36(0.21-0.61)‡
Admission to NICU	24(14.6%)	48 (30%)	26 (16%)	14.43	< 0.001	0.90(0.49-1.64)*
						2.24(1.31-3.84)†
						0.40(0.23-0.69)‡
Neonatal mortality	4 (2.4%)	12 (7.5%)	8 (4.9%)	4.42	0.12a	

**OR at 95% CI** = Odd's ratio at 95% Confidence interval, \*OR between Methyldopa and control group, †OR between Labetalol and control group, ‡OR between methyldopa and Labetalol group, a Fischer's exact test. # Yates correction was applied for the Chi-square test.



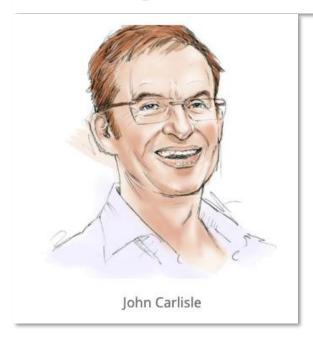
<sup>1.</sup> Moylan EC, Kowalczuk MK. Why articles are retracted: a retrospective cross-sectional study of retraction notices at BioMed Central. BMJ Open. 2016;6(11):e012047.

<sup>2.</sup> Chambers L, Michener C, Falcone T. Plagiarism and data falsification are the most common reasons for retracted publications in obstetrics and gynaecology. BJOG: An International Journal of Obstetrics & Gynaecology. 2019;126(9):1134-40.



# False individual patient data and zombie randomised controlled trials submitted to *Anaesthesia*

J. B. Carlisle<sup>1,2</sup>



# Hundreds of thousands of zombie randomised trials circulate among us

J. P. A. Ioannidis







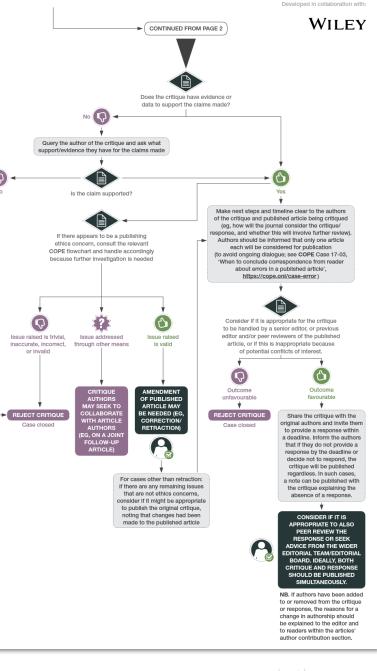




Notes Depending on the particular situation, it may be appropriate for an editor to facilitate a conversation A JOURNAL RECEIVES A CRITIQUE between both parties (eg, TO AN ARTICLE PREVIOUSLY if in regard to an issue which PUBLISHED IN THE JOURNAL. needs more clarification). If so, the editor should be copled in on the See COPE Core practice, conversations. Editorial 'Post-publication teams may wish to provide discussions and corrections', an anticipated timeline for https://cope.onl/corrections-2 Does the journal have this process from the outset a clearly defined and to avoid prolonged transparent policy for discussions without considering critiques resolution. Both parties (ie, available in their (the critique authors and author guidelines)? the authors of the critiqued article) should be informed of this timeline and encouraged to adhere to it. If delays are encountered/ expected, all parties should be kept informed. Proceed with further consideration Discuss with journal in line with journal policy team and publisher Is the content of the Does the journal wish to critique potentially consider the critique? libellous/defamatory? Does the content focus on the substance of the article rather Yes than comments directed towards the authors, institution, or funding agencies which may be deemed REJECT CRITIQUE Develop a defamatory or libellous? policy or Case closed peer review guidelines (Critique contains Critique contains reasonable content potentially libellous/ defamatory content Seek advice from your publishing team, who may consult their legal department for advice, and/or give the authors of the critique the opportunity to revise and remove the potentially libellous/ defamatory content to ensure that the content focuses only on the substance of the article If the content of the critique is confirmed to be libellous/defamatory and sufficient changes CONTINUES ON PAGE 3 are not made to correct

REJECT CRITIQUE

# HANDLING OF POST-PUBLICATION CRITIQUES





### Study Aim

To Quantify and Assess Publishers' and Editors Post-Publication Responses on Papers with Potential Untrustworthy Data in Women's Health



#### Methods

Data collection

Through independent reviews noted potential untrustworthy data

**Identifying Studies** 

Searched through online databases (eg. PubMed, PubPeer, Google Scholar)

E-mail correspondence with editors and publishers

Verified and noted initial correspondence and outcome dates



	Α	В	С	D	E	F	G	Н	I	J	
1	Date added (after 26-05-23)	Problematic Author	ID	Status -1= Insufficient Evidence/Not written, 0=Pending Investigation, 1=retract, 2=EoC, 2a= temporary removal, 3=Retr expected, 4= Editors note, 5= Investigation concluded no action, 6= Correction	Paper	Journal	Publisher	Additional Journal Information	Institution	Pubmedlink	F
251		Badawy	225	0	Badawy 2001	J Obstet Gynaecol	Taylor Francis		Mansoura University, ▼	https://pubmed.ncbi.nlm.nih.gov/1252190	Obse
252			226	0	Badawy 2003	J Obstet Gynaecol	Taylor Francis		Mansoura University, ▼	https://pubmed.ncbi.nlm.nih.gov/1285086	Coho
253			227	1	Badawy 2006	Fertil Steril	Elsevier		Mansoura University, ▼		RCT
254			228	0	Badawy 2007a	EJOG	Elsevier		Mansoura University, ▼	https://pubmed.ncbi.nlm.nih.gov/1712369	RCT
255			229	2	Badawy 2007b	Acta Obstet Gynecol Sca	Wiley Blackwell		Mansoura University, ▼	https://pubmed.ncbi.nlm.nih.gov/1736428	RCT
256			230	1	Badawy 2007c	RBM Online	Elsevier		Mansoura University, ▼		RCT
257			231	1	Badawy 2007d	RBM Online	Elsevier		Mansoura University, ▼		RCT
258			232	0	Badawy 2007e	J Obstet Gynaecol	Taylor Francis		Mansoura University, ▼	https://pubmed.ncbi.nlm.nih.gov/1770180	Coho
259			233	1	Badawy 2008a	J Obstet Gynaecol	Taylor Francis		Mansoura University, ▼		RCT
260			234	1	Badawy 2008b	Fertil Steril	Elsevier		Mansoura University, ▼		RCT
261			235	1	Badawy 2008c	RBM Online	Elsevier		Mansoura University, ▼		RCT
262			237	1	Badawy 2009a	Fertil Steril	Elsevier		Mansoura University, ▼		Coho
263			238	1	Badawy 2009b	Fertil Steril	Elsevier		Mansoura University, ▼		RCT
264			239	1	Badawy 2009c	Fertil Steril	Elsevier		Mansoura University, ▼		RCT
265			240		Badawy 2009d	Fertil Steril	Elsevier		Mansoura University, ▼		RCT
266			241		Badawy 2009e	Fertil Steril	Elsevier		Mansoura University, ▼		RCT
267			242		Badawy 2009f	Fertil Steril	Elsevier		Mansoura University, ▼		RCT
268			243	1	Badawy 2009g	Fertil Steril	Elsevier		Mansoura University, ▼		RCT
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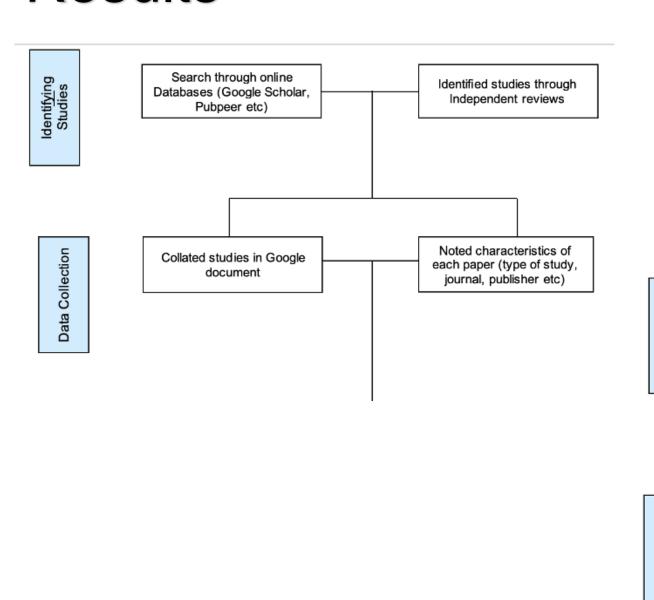


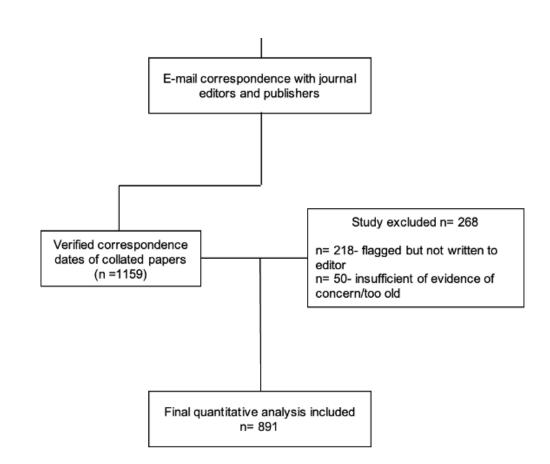
# Statistical Analysis

- Calculate the time taken from the original email written to editor outcome date [Retraction, Expression of Concern (EOC), etc]
- Kaplan-Meier analysis -
- Subgroup analysis Journal, publisher and country
- SPSS Version 29.0



#### Results





Screening

Included

#### Results

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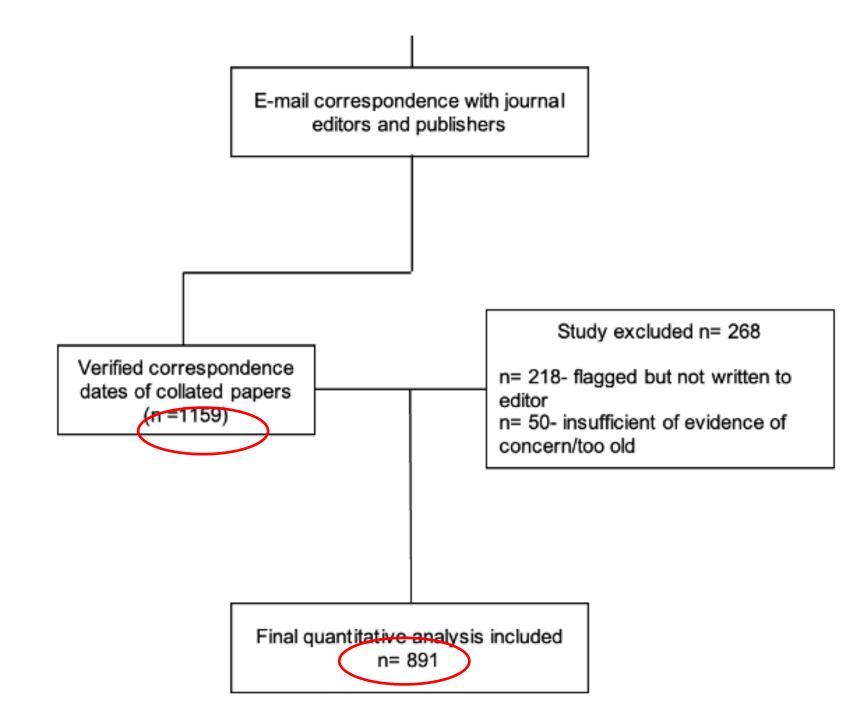
Data Collection

Search thr Databases (G Pubpe

Collated stud

Screening

Included



# Study characteristics

Table 1. Baseline Characteristics of Papers

			Status	3		
Characteristics	Retraction N = 151 <sup>1</sup>	Expression of Concern N = 75 <sup>1</sup>	Correction N = 6 <sup>1</sup>	Investigation concluded no action N = 30 <sup>1</sup>	Pending Investigation N = 629 <sup>1</sup>	Total
Publication year						
< 2000	1 (0.7%)	3 (4.0%)	0 (0%)	2 (6.7%)	6 (1.0%)	12 (1%)
2000-2010	27 (18%)	19 (25%)	0 (0%)	5 (17%)	94 (15%)	145 (16%)
2010-2020	89 (59%)	47 (63%)	4 (67%)	11 (37%)	376 (60%)	527 (59%)
2020-Present	34 (23%)	6 (8.0%)	2 (33%)	12 (40%)	153 (24%)	207 (23%)
Type of study						
Observational	40 (26.4%)	25 (33%)	1 (17%)	5 (17%)	292 (46.6%)	363 (41%)
RCT	111 (80%)	50 (67%)	5 (83%)	25 (83%)	337 (53.4%)	528 (59%)
Country of origin						
Middle East	141 (93%)	73 (96%)	6 (100%)	19 (63.3%)	551 (86.8%)	790 (86%)
Europe	6 (3.9%)	2 (2.7%)	0 (0%)	3 (10%)	73 (7.0%)	84 (9%)
Asia	4 (2.7%)	1 (1.3%)	0 (0%)	8 (26.7%)	27 (4.3%)	40 (4%)
Other (USA, Brazil	0 (0%)	0 (0%)	0 (0%)	0 (0%)	7 (1.1%)	
and Tunisa)						7 (1%)
Year 1st email sent						
2017	2 (1.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (0.1%)
2019	5 (3.3%)	12 (16%)	0 (0%)	1 (3.3%)	1 (0.2%)	19 (2%)
2020	34 (23%)	10 (14%)	0 (0%)	2 (6.7%)	16 (2.5%)	62 (7%)
2021	64 (43%)	17 (23%)	2 (33%)	7 (23%)	96 (15%)	186 (21%)
2022	39 (25%)	28 (36%)	4 (67%)	8 (27%)	273 (43%)	352 (40%)
2023	7 (4.7%)	8 (11%)	0 (0%)	12 (40%)	172 (27%)	199 (22%)
2024	0 (0%)	0 (0%)	0 (0%)	0 (0%)	70 (11%)	70 (8%)

<sup>&</sup>lt;sup>1</sup> Data are n (%) unless otherwise specified.



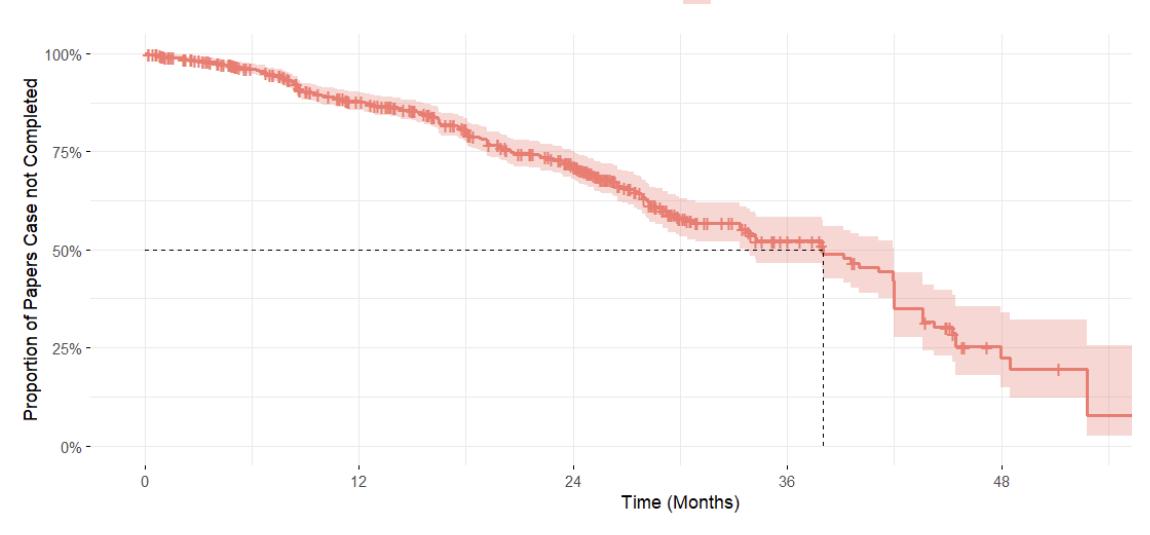
# Outcome of post-publication of papers

Status	N=891	Assessment Outcome (%)
Completed investigation	262	25
Retraction	151	16.9
Expression of concern	75	8.4
No wrongdoing found	30	3.4
Correction	6	0.7
Pending	629	70.6



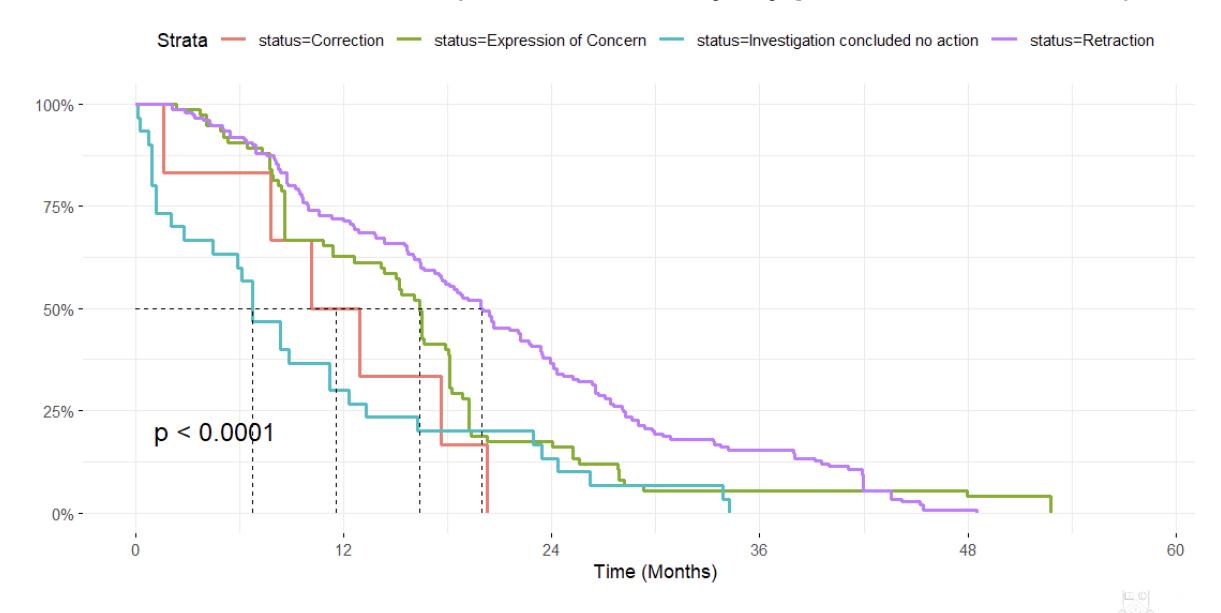
### Time To decision

Strata 🛨 📶





# Time To decision (stratified by type of decision)



### Publisher's Time To Response

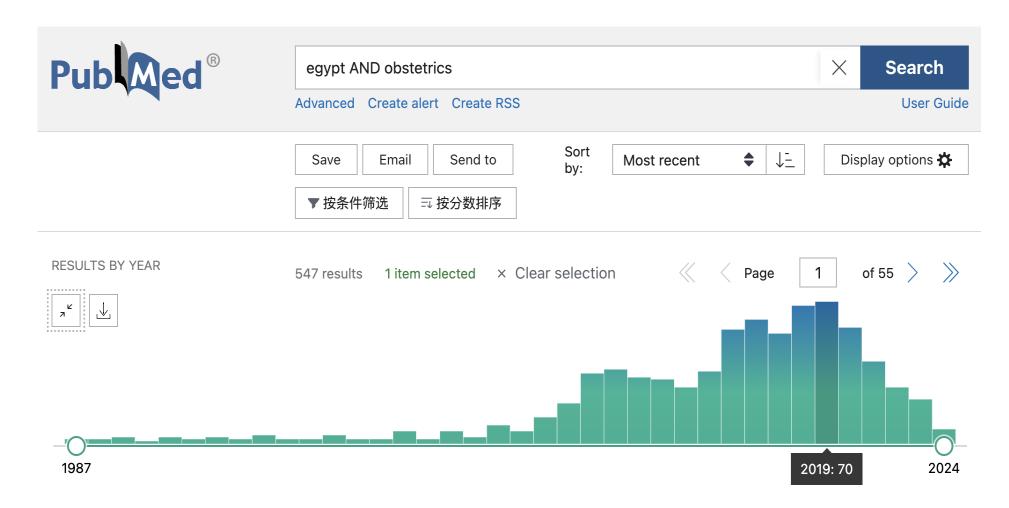
Publishe rs & Societies (n=73)	No: of Flagged Papers (N=732)	Case Completi on Rate (N,%)	Retrac- ted	EOC	Correc- tion	No Wrong- doing	Pending	Median Time To Response (Months)
Elsevier	165	40 (24%)	27	8	1	4	125	40
Taylor & Francis	140	48 (34%)	28	20	0	0	92	26
Springer	133	35 (26%)	19	11	2	3	98	44
Wiley Blackwell	102	21 (21%)	10	8	0	3	81	33
Wolters Kluwer	43	22 (51%)	5	14	0	3	21	16



## Journal Time To Response

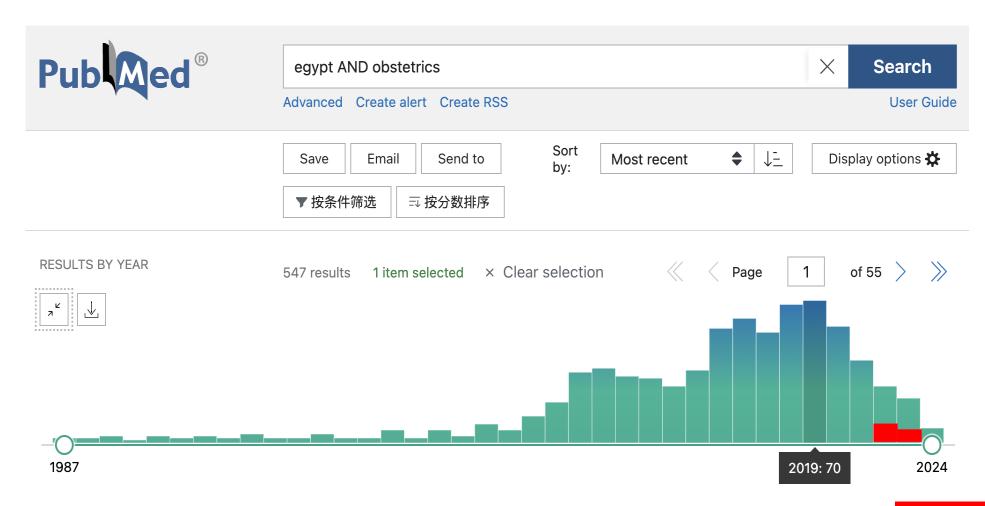
Status	Number of flagged Papers	Case Completion Rate (%)	Retraction	Expression of Concern	Correction	Investigation concluded no action	Pending Investi- gation	Median Time to Response (Days)	Median Time to Response (Months)
J Matern Fetal Neonatal Med	78 (8.8%)	29 (37%)	11 (7.3%)	18 (24%)	0 (0%)	0 (0%)	49 (7.8%)	594	20
Int J Gynaecol Obstet	67 (7.5%)	22 (33%)	12 (7.9%)	0 (0%)	0 (0%)	10 (33%)	45 (7.2%)	724	24
Fertil Steril	57 (6.4%)	24 (41%)	14 (9.3%)	2 (2.7%)	1 (17%)	4 (13%)	36 (5.7%)	319	11
EJOG	38 (4.3%)	16 (42%)	14 (9.3%)	2 (2.7%)	0 (0%)	0 (0%)	22 (3.5%)	522	17
Eur J Contracept Reprod Health Care	24 (2.7%)	19 (75%)	18 (12%)	0 (0%)	0 (0%)	1 (4%)	5 (1.0%)	465	16
J Obstet Gynaecol	23 (2.6%)	12 (52%)	12 (7.9%)	0 (0%)	0 (0%)	0 (0%)	11 (1.7%)	739	25
J Urol	15 (1.7%)	14 (93%)	0 (0%)	14 (19%)	0 (0%)	0 (0%)	1 (0.2%)	258	9

#### RCTs from Egypt (PubMed)





#### RCTs from Egypt (PubMed)



BMC Pregnancy and Childbirth



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#### **Editorial Board**

Tovah Honor Aronin, Ph.D. - Senior Editor, BMC series



Tovah Honor Aronin has been an Editor for BMC since 2016 and has been working on *BMC Pregnancy and Childbirth* since 2017. Before moving into publishing, Tovah received her Ph.D. from Johns Hopkins University Baltimore, USA, where she studied calcium signaling in yeast, developing a novel microscopy probe for real-time measurement of calcineurin activity. An early fascination with Punnett squares lead to a focus on genetics, which then broadened into an interest in the communication and application of scientific research across disciplines. Tovah is an editor for the *BMC* series blog and is interested in promoting best

practices in health care.

6 RCTs In BMC in 2022/23

1x Ahmed Maged



1x Ahmed Abbas



4x Mazen Abel-Rasheed





#### The Economist

Science & technology | Scientific malpractice

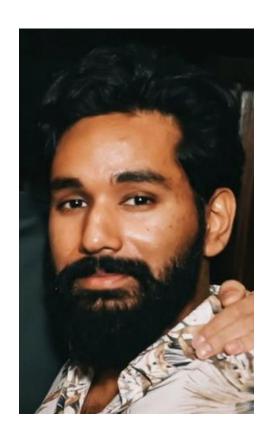
There is a worrying amount of fraud in medical research

And a worrying unwillingness to do anything about it



- The current post-publication review process is slow to issue an outcome
- Majority of investigated papers led to retractions/EOC
- Study shows a small percentage of a bigger problem in women's health
- Harmful to mothers and babies





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Siddharth Shivantha Nicole Au Jim Thornton Jeremy Nielsen Sue Liu Maddy Flanagan Madelon van Wely May Myat Linn Yizhen Liu Esmee Bordewijk
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Rui Wang
John Carlisle
John Loadsman
Jack Wilkinson
Will Spratt
Jessica Srivastava
Nishat Siddique

Many anonymous informers

Many positive responses on my morning talk



From:

**Date:** Tuesday, 4 June 2024 at 1:06 pm **To:** Ben Mol <Ben.Mol@monash.edu>

Subject: WCRI talk

Hi Ben

Your talk was really moving. What a shitshow!

So problem is everyone is winning:

- Authors get h-index
- Institutions get published research
- Publishers make money
- COPE says they are good policemen

Only as you say women and children suffer, but who cares :-(

I can't help thinking it's the Dutch in you that keeps the fight going. Bit like Elisabeth Bik. You say what you feel, unlike the British say!

Thanks for the talk.

Regards



