# A core outcome set for future male infertility research: development of an international consensus†

Michael P. Rimmer,[1,2] Ruth A. Howie,[2] Richard A. Anderson,[1,2] Christopher L. R. Barratt,[3] Kurt T. Barnhart,[4] Yusuf Beebeejaun,[5] Ricardo Pimenta Bertolla,[6,7] Pietro Bortoletto,[8] Robert E. Brannigan,[9] Astrid E. P. Cantineau,[10] Ettore Caroppo,[11] Barbara L. Collura,[12] Kevin Coward,[13] William Colin Duncan,[1,2] Michael L. Eisenberg,[14] Steven A. Gellatly,[3] Christian De Geyter,[15] Dimitrios G. Goulis,[16] Ralf R. Henkel,[17,18,19] Vu N. A. Ho,[20] Alayman F. Hussein,[21] Carin Huyser,[22] Jozef H. Kadijk,[23] Mohan S. Kamath,[24] Shadi Khashaba,[25,26] Hajra Khattak,[27] Yoshitomo Kobori,[28] Julia Kopeika,[29] Tansu Kucuk,[30] Saturnino Luján,[31] Thabo Christopher Matsaseng,[32,33] Raj S. Mathur,[34] Kevin McEleny,[35] Rod T. Mitchell,[1] Ben W. Mol,[36] Alfred M. Murage,[37] Ernest H. Y. Ng,[38] Allan Pacey,[39] Antti H. Perheentupa,[40] Stefan Du Plessis,[41,42] Nathalie Rives,[43] Ippokratis Sarris,[5,44] Peter N. Schlegel,[45] Majid Shabbir,[29] Maciej Śmiechowski,[46,47] Venkatesh Subramanian,[5] Sesh K. Sunkara,[44] Basil C. Tarlarzis,[16] Frank Tüttelmann,[48] Andy Vail,[49] Madelon van Wely,[50,51] Mónica H. Vazquez-Levin,[52] Lan N. Vuong,[53] Alex Y. Wang,[54] Rui Wang,[55] James M. N. Duffy,[56,57] Cindy M. Farquhar,[58,59] and Craig Niederberger[60,61]

[1]Centre for Reproductive Health, Institute of Regeneration and Repair, University of Edinburgh, Edinburgh, United Kingdom; [2]Edinburgh Fertility Centre, Simpsons Centre for Reproductive Health, Royal Infirmary of Edinburgh, Edinburgh, United Kingdom; [3]Reproductive Medicine Research Group, Ninewells Hospital and Medical School, University of Dundee, Dundee, United Kingdom; [4]Department of Obstetrics and Gynaecology, University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania, USA; [5]King's Fertility, The Fetal Medicine Research Institute, King's College London, London, United Kingdom; [6]Division of Urology, Department of Surgery, Universidade Federal de Sao Paulo, Sao Paulo, Brazil; [7]Department of Obstetrics and Gynecology, School of Medicine, C.S. Mott Center for Human Growth and Development, Wayne State University, Detroit, Michigan, USA; [8]Boston IVF, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA; [9]Feinberg School of Medicine, Northwestern University, Chicago, Illinois, USA; [10]Centre of Reproductive Medicine, University of Groningen, University Medical Centre Groningen, Groningen, The Netherlands; [11]ASL Bari, Andrology Outpatients Clinic, Conversano, Italy; [12]RESOLVE: The National Infertility Association, USA; [13]Nuffield Department of Women's & Reproductive Health, University of Oxford, Level 3, Women's Centre, John Radcliffe Hospital, Oxford, United Kingdom; [14]Stanford University, Stanford, California, USA; [15]Reproductive Medicine and Gynaecological Endocrinology (RME), University Hospital, University of Basel, Basel, Switzerland; [16]Units of Human Reproduction and Reproductive Endocrinology, 1st Department of Obstetrics and Gynaecology, Medical School, Aristotle University of Thessaloniki, Thessaloniki, Greece; [17]Department of Digestion, Metabolism and Reproduction, Imperial College London, London, United Kingdom; [18]Department of Medical Bioscience, University of the Western Cape, Bellville, South Africa; [19]LogixX Pharma Ltd., Theale, United Kingdom; [20]IVFMD and HOPE Research Centre, My Duc Hospital, Ho Chi Minh City, Vietnam; [21]Minia University, Minia, Egypt; [22]Reproductive Biology Laboratory, Department of Obstetrics and Gynaecology, University of Pretoria, Pretoria, South Africa; [23]Freya—Dutch Patient

† This article has been co-published with permission in Fertility and Sterility and Human Reproduction. The articles are identical except for minor stylistic and spelling differences in keeping with each journal's style.

**Study Funding/Competing Interest(s):** This work was funded by The Urology Foundation, Small Project Fund awarded to Michael P Rimmer at the University of Edinburgh, UK. RTM was supported by a United Kingdom Research and Innovation (UKRI) Future Leaders Fellowship (MR/Y011783/1). C.L.R.B. is the co-editor in chief of *Human Reproduction* and recipient of a BMGF grant and received consultancy fees from Exscentia and Exceed sperm testing, paid to the University of Dundee and speaking fees or honoraria paid personally by Ferring, Copper Surgical and RBMO. R.P.B. receives royalties from Flow diagnósticos. M.L.E. is an advisor to the companies Hannah, Illumicell, Next, Legacy, Doveras, Vseat and received a consultancy fee for this. B.W.M. is a paid consultant for Norgine and Organon and has received research funding from Ferring and Merck, he also receives consultancy and travel support from Merck. R.R.H. received royalties from Elsevier for a book, consultancy fees from Glyciome, and presentation fees from GryNumber Health and Aytu Bioscience. Attendance at Fertility 2020 and Roadshow South Africa by Ralf Henkel was funded by LogixX Pharma Ltd. R.R.H. is also Editor in Chief of *Andrologia* and has been an employee of LogixX Pharma Ltd. since 2020. M.S.K. has been an associate editor with *Human Reproduction Open*. K.Mc.E. received funding to attend Fertility 2025 by the British Fertility Society and is the Chair of the British Fertility Society. He is a member of the HFEA's Scientific and Clinical Advances Advisory Committee and a Committee Member of the NICE Fertility Problems Guideline Group. M.H.V.L. receives consultation fees for the WHO Manual Spanish translation, and travel expenses for the ESHRE MRHI meeting in Budapest. She is a member of the editorial board for *Fertility & Sterility*, *F&S Science*, *Human Reproduction*, and *Frontiers in Endocrinology*. She is also a panel member of the World Health Organization (WHO) Human Reproduction Programme (HRP) Research Project Review Panel. R.S.M. is a member of the NICE Guideline Committee on Fertility and former chair of the British Fertility Society. A. Perheentupa receives an honoraria for lecturing from Merck for the Tackling Infertility manifest, Gedeon Richter & Ferring. A. Perheentupa declares lecture honoraria from Merck, Gideon Richter, and Ferring; and payment from Merck for the Tackling Infertility manifesto. A. Pacey receives consultancy fees for Carrot Fertility and Cryos International as well as lecturing for IBSA Institut Biochimique SA and Mealis Group—all fees paid to The University of Manchester. He is also a Trustee of Progress Educational. Trust (Charity Number 1139856) and Chairman of UKNEQAS Reproductive Sciences Advisory Committee. F.T. is the recipient of a Bayer research grant, as well as DFG Clinical Research Unit 'Male Germ Cells' (CRU326, project number 329621271) and BMBF Junior Scientist Research Centre 'ReproTrack.MS' (grant 01GR2303), he has received travel support from IBSA and Organon. M.v.W. is the Editor-in-Chief of *Human Reproduction Update*. R.W. is a former Deputy Editor of *Human Reproduction* and is currently a Deputy Editor of *Human Reproduction Update*.

Correspondence: Michael P. Rimmer, Centre for Reproductive Health, Institute of Regeneration and Repair, University of Edinburgh, Edinburgh, UK (E-mail: michael.rimmer@ed.ac.uk).

Fertil Steril® Vol. 123, No. 6, June 2025 0015-0282



https://doi.org/10.1016/j.fertnstert.2025.03.009

Association for Infertility, Gorinchem, The Netherlands; [24]Department of Reproductive Medicine and Surgery, Christian Medical College, Vellore, India; [25]University of New South Wales, Sydney, Australia; [26]IVF Australia, Sydney, Australia; [27]Department of Reproductive Health, Elizabeth Garrett Anderson Institute for Women's Health, University College London, London, United Kingdom; [28]Dokkyo Medical University Saitama Medical Center, Koshigaya, Japan; [29]Guy's & St Thomas' Hospital NHS Trust, London, United Kingdom; [30]Acibadem Maslak Hospital, Istanbul, Turkey; [31]Urology Department, Hospital Universitari i Politècnic La Fe, Valencia, Spain; [32]Department of Obstetrics & Gynaecology, Stellenbosch University, Stellenbosch, Western Cape, South Africa; [33]Tygerberg Academic Hospital, Cape Town, South Africa; [34]Manchester University Foundation Trust, Manchester Academic Health Sciences Centre, Manchester, United Kingdom; [35]Newcastle Fertility, The Newcastle upon Tyne Hospitals NHS Trust, Newcastle, United Kingdom; [36]Department of Obstetrics and Gynaecology, Monash University, Clayton, Australia; [37]Harley Street Fertility Centre, Nairobi, Kenya; [38]Department of Obstetrics and Gynaecology, The University of Hong Kong, Hong Kong Special Administrative Region, Hong Kong, China; [39]School of Medical Sciences, Faculty of Biology, Medicine and Health, University of Manchester, Manchester, United Kingdom; [40]Department of Obstetrics and Gynaecology, University of Turku and Turku University Hospital, Turku, Finland; [41]College of Medicine, Mohammed Bin Rashid University of Medicine and Health Sciences, Dubai, UAE; [42]Medical Physiology, Stellenbosch University, Tygerberg, South Africa; [43]Univ Rouen Normandie, Inserm U1239, NorDIC, Team "Adrenal and Gonadal Pathophysiology", Rouen University Hospital, Biology of Reproduction-CECOS Laboratory, Rouen, France; [44]Faculty of Life Sciences and Medicine, King's College London, London, United Kingdom; [45]New York Men's Health, PLLC, New York, New York, USA; [46]Association for Infertility Treatment and Adoption Support "Our Stork", Warsaw, Poland; [47]Fertility Europe VZW, Evere, Belgium; [48]Centre of Medical Genetics, Institute of Reproductive Genetics, University of Münster, Münster, Germany; [49]Centre for Biostatistics, University of Manchester, Manchester Academic Health Science Centre, Manchester, United Kingdom; [50]Netherlands Satellite of the Cochrane Gynaecology and Fertility Group, Centre for Reproductive Medicine, Amsterdam, Netherlands; [51]Reproduction & Development Research Institute, Amsterdam University Medical Centre, Amsterdam, Netherlands; [52]Laboratorio de Estudios de Interacción Celular en Reproducción y Cáncer. Instituto de Biología y Medicina Experimental (IBYME), Consejo Nacional de Investigaciones Científicas y Técnicas de Argentina (CONICET), Buenos Aires, Argentina; [53]Department of Obstetrics and Gynaecology, University of Medicine and Pharmacy at Ho Chi Minh City, Ho Chi Minh City, Vietnam; [54]Faculty of Health, University of Technology Sydney, Sydney, Australia; [55]NHMRC Clinical Trials Centre, University of Sydney, Sydney, Australia; [56]Centre for Reproductive Medicine, St Bartholomew's Hospital, Barts Health NHS Trust, London, United Kingdom; [57]Department of Women's Health, Kings College London, London, United Kingdom; [58]Cochrane Gynaecology and Fertility Group, Auckland, New Zealand; [59]Department of Obstetrics and Gynaecology, University of Auckland, Auckland, New Zealand; [60]Department of Urology, University of Illinois at Chicago, Chicago, Illinois, USA; [61]Department of Bioengineering, University of Illinois at Chicago College of Engineering, Chicago, Illinois, USA

**Objective:** To develop a core outcome set for male infertility trials.
**Design:** A two-round Delphi survey and consensus development workshop were undertaken with healthcare professionals, researchers and clinicians globally.
**Subjects:** 334 participants from 39 countries participated in the Delphi Survey, while 44 participants from 21 countries participated in the consensus development workshop.
**Exposure:** NA
**Main Outcome Measures:** The core outcome set for male infertility trials has been developed by the inclusion of specific male-factor outcomes in addition to the general infertility core outcome set which focuses on female-factor outcomes.
**Results:** The outcomes identified include assessment of semen using the World Health Organisation recommendations for semen analysis; viable intrauterine pregnancy confirmed by ultrasound (accounting for singleton, twin and higher multiple pregnancies); pregnancy loss (accounting for ectopic pregnancy, miscarriage, stillbirth and termination of pregnancy); live birth; gestational age at delivery; birthweight; neonatal mortality; and major congenital anomaly. Although not a requirement as part of the core outcome set, other outcomes were identified as potentially useful in certain study settings.
**Conclusion:** Embedding the core outcome set within RCTs and systematic reviews should ensure the comprehensive selection, collection and reporting of core outcomes, which are inconsistently reported at present. Research funding bodies, the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement, and over 80 specialty journals, including the Cochrane Gynaecology and Fertility Group, *Fertility and Sterility* and *Human Reproduction*, have committed to implementing this core outcome set for male infertility trials.
**Trial Registration Number:** Core Outcome Measures in Effectiveness Trials (COMET) initiative registration No: 1586. Available at www.comet-initiative.org/Studies/Details/1586. (Fertil Steril® 2025;123:1017–28. ©2025 by American Society for Reproductive Medicine.)
**El resumen está disponible en Español al final del artículo.**

**Keywords:** consensus development study, core outcome sets, Delphi survey, male infertility, outcome measures, outcomes, randomized control trials

## INTRODUCTION

Male infertility is recognized as a contributing factor in around 40–50% of couples struggling to conceive (1–6), and it is estimated that around 1 in 10 men are infertile (3, 6–9). There is an urgent need to evaluate the safety and efficacy of interventions to treat male infertility through well-designed, well-conducted, and reported randomized controlled trials (RCTs) (10). Despite their robust design, RCTs are only as meaningful as the outcomes they collect and report (11). A recent systematic review of the 100 largest RCTs in male infertility published in the last 10 years identified substantial heterogeneity in outcome reporting and how these outcomes were measured and defined (12). This can lead to barriers in evaluating the efficacy of interventions to achieve their desired effect and limit their implementation into clinical practice.

Examples of inconsistent outcome reporting in male infertility trials include the pregnancy rate, reported by only 51/100 trials, using 12 different definitions or no definition at all. The 12 definitions varied greatly, from a serum human chorionic gonadotrophin hormone (hCG) >25 IU/l to the presence of a gestational sac on ultrasound scan (USS) to a viable foetus on transvaginal USS. Another example would be live birth, reported by only 13/100 trials and defined in two different ways or not at all.

Such variation allows researchers to selectively report favourable results based on statistical significance. Selective reporting of outcomes based on statistical significance can result in overestimating treatment efficacy and underestimating harm (11). Evidence synthesis can be challenging without consistent outcome selection, collection, and reporting, making comparisons and combining these data within a meta-analysis impossible.

These issues can be addressed by developing a core outcome set for RCTs and systematic reviews. A core outcome set represents a minimum collection of important outcomes and outcome measures which have been developed using formal consensus methods engaging healthcare professionals, researchers, and people with fertility problems. Core outcomes should be routinely utilized by researchers, collected in a standardized manner, and reported consistently in the final publication (13).

Historically, research design has placed limited emphasis on engaging with individuals experiencing fertility problems. This lack of engagement may have inadvertently resulted in researchers prioritizing outcomes based on their own preferences.

In recent years, there has been increasing involvement of patients and the wider public in the design and conduct of research. This involvement is pivotal to shaping the development of future core outcome sets and the design of RCTs.

While a core outcome set for general infertility trials has been developed and has a focus predominantly on female infertility, no such outcome set exists for male infertility (14, 15). While most RCTs have an individual receiving an intervention and that individual is followed up and outcomes reported, male infertility trials are unique in that they potentially include three relevant participants: the male participant receiving an intervention, their female partner providing gametes and/or carrying a pregnancy and their potential offspring, for which all participants have potentially relevant outcomes. This highlights the need for a patient-centred core outcome set to be developed specifically for male infertility RCTs.

Motivated by the desire to increase the quality and consistency of future male infertility research, an international collaboration of clinicians, researchers, and people with fertility problems have been brought together to develop a core outcome set for future infertility research.

## MATERIALS AND METHODS

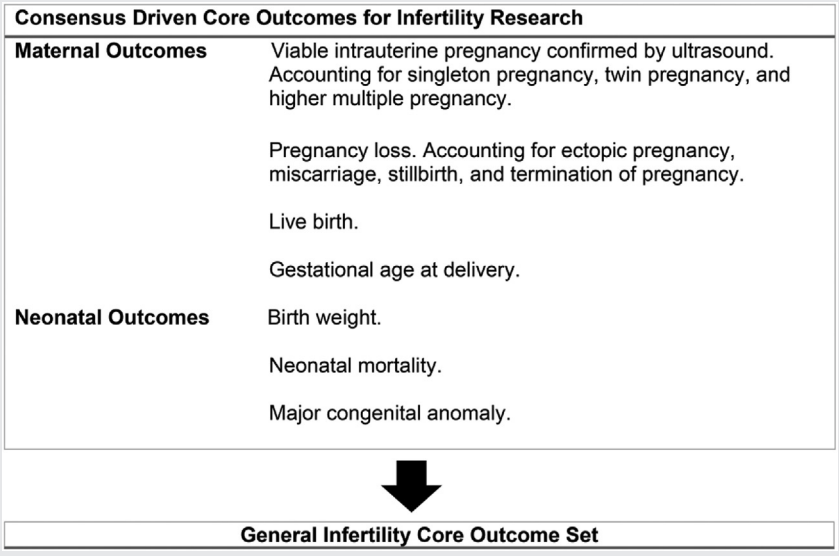
The study was prospectively registered with the Core Outcome Measures in Effectiveness Trials (COMET) initiative, registration number 1586. An international steering group, including healthcare professionals, researchers, and people with infertility, was established. This steering group developed the study protocol to conduct this work and undertook a systematic review to identify the outcomes used in male infertility trials to advise on participant samples, data collection, and data analysis (12, 16).

This male infertility core outcome set was developed in a three-stage process using consensus science methods advocated by the COMET initiative (17). First, a systematic review of the 100 largest RCTs in male infertility trials in the last ten years was conducted to identify the outcomes reported and identify heterogeneity in outcome selection, reporting, or definitions (12). Data from the systematic review were used to develop a protocol for guidance on how this core outcome set would be developed and has previously been published (16). The expertise of the steering group and past core outcome set development was also used to guide the development of the protocol (18).

A comprehensive inventory of outcomes was developed by extracting primary and secondary outcomes from our systematic review (12). Lay definitions were developed for individual outcomes and entered into a modified Delphi (19). A core outcome set for infertility research, with a focus on female infertility, has been developed, and it was proposed these outcomes would be included in a male infertility outcome set given the overlap with key outcomes such as pregnancy and live birth (Fig. 1) (15). The outcomes of live birth and gestational age at delivery were not included in the Delphi survey as these have been clearly defined and selected in past core outcome sets and would automatically be included in this male infertility outcome set (14).

We sought to recruit key stakeholders, including healthcare professionals, researchers, and men and women with fertility problems. Healthcare professionals and researchers were recruited through professional networks, the Core Outcomes in Women's and Newborn Health initiative, and the Cochrane Gynaecology and Fertility Group. Men and women with fertility problems were recruited through Fertility Europe (www.fertilityeurope.eu/), Fertility Network UK (www.fertilitynetworkuk.org/), Fertility New Zealand (www.fertilitynz.org.nz/), and Freya (www.freyafertility.dk)—an association for people with fertility problems. Project

**FIGURE 1**




Core outcome set for general infertility research.

*Rimmer. A core outcome set for male infertility research. Fertil Steril 2025.*

dissemination and stakeholder engagement were supported through social media campaigns.

The Delphi method does not depend on statistical power. Working from its underlying principles, group error should decrease and the decision quality should increase as the number of participants rises. Between 10 and 15 participants have been demonstrated to yield sufficient results and assure validity in past Delphi surveys (19). Anticipating a 20% attrition rate, we aimed to recruit 18 participants from the three stakeholder groups.

The modified Delphi method was delivered through sequential online surveys using Delphi survey software (Delphi Manager, University of Liverpool, Liverpool, UK). In round one of the survey, potential participants received a summary in plain language, Delphi survey instructions, and an explanatory video on the purpose of Delphi. Participants were invited to score individual outcomes on a nine-point Likert scale, and they could leave a category unscored if they did not wish to offer a score. Before completing the survey, participants were able to suggest additional outcomes.

After the round one survey closed, the scores for each outcome were aggregated across individual stakeholder groups. The percentage of participants scoring each outcome at every possible response from one to nine was calculated and tabulated for individual stakeholder groups. The steering group considered additional outcomes, and novel outcomes were entered into the round two survey.

In round two, participants were asked to reflect on their scores and the scores of other participants before rescoring each outcome. Before completing the survey, participants could score additional outcomes suggested by participants in the round one survey. An outcome was considered to have reached a consensus if more than 70% of each stakeholder group scored it as either 7, 8, or 9 (16).

The steering group reviewed the results of the Delphi survey in round two to determine whether a further round was required. The steering group members concluded that it was unlikely that a further round would identify additional consensus outcomes based on the past core outcome set development (14, 15, 20). Following the completion of the survey, online consensus development meetings were arranged.

A modified nominal group technique was used to prioritize consensus outcomes further. Stakeholders who had completed both rounds of the Delphi survey were invited to participate. The modified Nominal Group Technique does not depend on statistical power. In consultation with the steering group, we aimed to recruit between 10 and 15 participants, as this number has yielded sufficient results and assured validity in other settings (19).

At the beginning of the meeting, the results of the Delphi survey were reviewed. Potential core outcomes reaching the standardized consensus definition were entered into the process. Outcomes which met the consensus criteria which were already included in the Core Outcome Set for Infertility Trials were omitted from discussions as these would be automatically included in future male infertility trials (Fig. 1) (14, 15). Participants could enter other potential core outcomes that had not reached the standardized consensus definition upon request. Participants were invited to contribute their opinions on the proposed outcomes to be included.

During the consensus meeting, discussions focused on the outcomes to be included in the core outcome set. Following the consensus meetings, outcomes were divided into three

initial outcome categories: those (i) to be included in the final core outcome set, (ii) on which some consensus was reached and which may be advantageous to include in specific circumstances, and (iii) that were not included.

## RESULTS

Our systematic review of the 100 largest RCTs in the past 10 years developed an inventory of 79 outcomes. We combined different definitions of a single outcome into a single definition, resulting in 52 outcomes to be input into the Delphi. Outcomes were grouped into nine domains, including semen analysis, pregnancy outcomes, neonatal outcomes, maternal outcomes, lifestyle factors, clinical findings, operative and post-operative outcomes, and additional suggested outcomes (Supplementary Table S1).

Round one of the Delphi survey received 334 responses from individuals in 39 countries, including 267 healthcare professionals, 36 researchers, and 31 people with fertility problems (Table 1). Round two received 216 responses from individuals in 39 countries, including 164 healthcare professionals, 29 researchers, and 23 people with fertility problems (Table 1). In addition to the 52 outcomes input into the Delphi in round one, following additional suggested outcomes, a further 11 outcomes were entered in round two, meaning a total of 63 outcomes were considered (Fig. 2).

The consensus development meetings were held after round 2 of the Delphi for North/South America, Africa/Europe, and Asia/Australia. This included 24 healthcare professionals, 17 researchers, and 3 people with fertility problems from 21 countries. Nineteen consensus outcomes were entered into the modified Nominal Group Technique; outcomes that were included in the core outcome set for general infertility trials were automatically included in the core outcome set for male fertility trials. Participants prioritized outcomes for inclusion in the core outcome set for male infertility (Fig. 3). Although some outcomes discussed were not entered into the final core outcome set, members of the consensus development meetings highlighted they may be of utility in trials with a particular study design or specific outcome (Fig. 4). These outcomes included chromosomal abnormalities, ejaculatory and sexual dysfunction, testicular atrophy and testicular volume, as well as serum quantification of testosterone and follicle-stimulating hormone (FSH).

## DISCUSSION

We sought to develop a core outcome set for male infertility research using formal consensus science methods. In this study, an international collaboration of healthcare professionals, researchers, and people with fertility problems have developed a core outcome set that should be used to standardize outcome selection, collection, and reporting in male infertility RCTs and systematic reviews.

To our knowledge, this is the first core outcome set developed focusing on male infertility trials and follows on from similar initiatives such as the 'Addressing male patients with hypogonadism and/or infertility owing to altered, idiopathic testicular function' (APHRODITE) criteria (22). We used our systematic review of the 100 largest RCTs in male

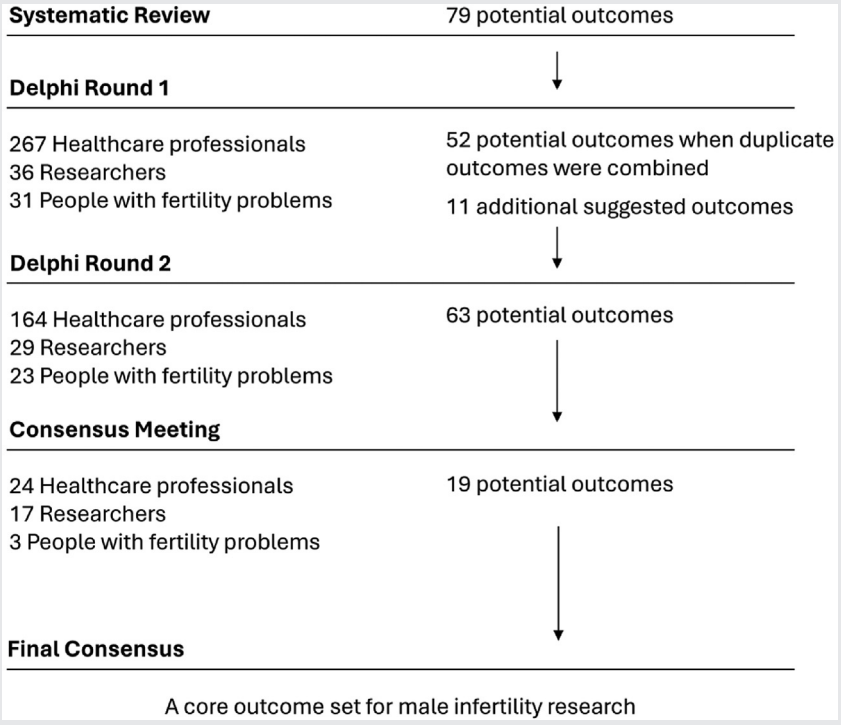
**TABLE 1**

**Delphi participant characteristics in rounds 1 and 2.**

| | Round 1 n = 334 | Round 2 n = 216 | Withdrawals n = 118 | Consensus development meeting n = 44 |
|---|---|---|---|---|
| **Stakeholder group, n** | | | | |
| Healthcare professionals | 267 | 164 | 103 | 24 |
| Researchers | 36 | 29 | 7 | 17 |
| Patients with infertility | 31 | 23 | 8 | 3 |
| **Gender, n** | | | | |
| Male | 189 | 132 | 57 | 33 |
| Female | 144 | 83 | 61 | 11 |
| Prefer not to say | 1 | 1 | 0 | 0 |
| **Age (years), n** | | | | |
| Under 29 | 19 | 15 | 4 | 0 |
| 30–39 | 100 | 66 | 34 | 8 |
| 40–49 | 103 | 61 | 42 | 19 |
| 50–59 | 68 | 44 | 24 | 13 |
| Over 60 | 42 | 30 | 12 | 4 |
| Prefer not to say | 2 | 0 | 2 | 0 |
| **Geographical location, n** | | | | |
| Africa | 23 | 14 | 9 | 1 |
| Asia | 63 | 47 | 16 | 9 |
| Australia and New Zealand | 20 | 12 | 8 | 3 |
| Europe | 140 | 86 | 54 | 20 |
| North America | 41 | 31 | 10 | 5 |
| South America | 47 | 26 | 21 | 6 |
| Prefer not to say | 0 | 0 | 0 | 0 |

*Rimmer. A core outcome set for male infertility research. Fertil Steril 2025.*

**FIGURE 2**




Flowchart of participants and outcomes.

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infertility conducted in the last 10 years to develop a comprehensive inventory of outcomes to be considered in our Delphi. From these, 20 individual outcomes were identified (Fig. 3) and have been defined in a previous consensus statement or using the WHO semen analysis manual (21, 23). These related to paternal, maternal, and neonatal outcomes that should be assessed, collected, and reported.

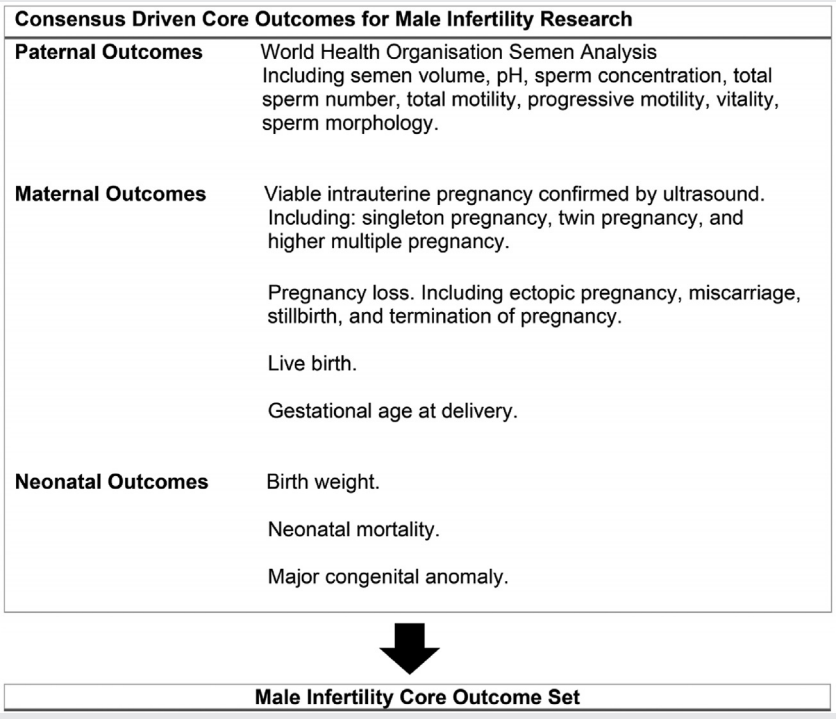
The COMET initiative has published guidance on the standards expected when developing a core outcome set (24). The outcome set reported in this study meets these standards. With 334 participants from 39 countries participating in the Delphi survey and 44 participants from 21 countries participating in the consensus development meeting, the global participation achieved in this study should secure the generalizability of the results across diverse research settings.

In addition to healthcare professionals and researchers, this study included people with fertility problems as steering group members and participants. As participants, they shared their views regarding the importance of potential core outcomes during the Delphi survey and participated in the consensus development meeting. This contribution should ensure the final core outcome set holds the necessary reach and relevance to men with infertility.

The core outcome set for infertility research was the basis of this core outcome set for male infertility research (15). Through an independent Delphi process, we identified the same core outcomes, including viable intrauterine pregnancy, pregnancy loss, and neonatal morbidity, which validate the inclusion of these outcomes and the process undertaken in developing a male infertility core outcome set.

While this study has established a core outcome set for male infertility, different definitions exist for individual core outcomes. Previous consensus work as part of the Core Outcome Measures in Infertility Trials (COMMIT) initiative has developed standardized definitions, using formal consensus development methods, for many of the outcomes included in this outcome set (20). The outcomes for which a COMMIT-led definition has not been developed include those identified as part of the World Health Organization (WHO) recommendations for semen analysis. These eight criteria include semen volume, pH, sperm concentration, total sperm number, total motility, progressive motility, vitality, and sperm morphology. Their definition and measurement are defined in the 6th edition of the WHO laboratory manual for examining and processing of human semen (21). Guidance on how semen analysis should be undertaken and laboratory standards to be followed are outlined by the International Organization for Standardization guidance on the minimum requirements for equipment and test methods for basic semen analysis (25). As such, no additional consensus or definition development was undertaken. During the consensus development meeting, it was decided that as the WHO laboratory manual for examining and processing human semen is updated, this updated set of definitions and assessment criteria should be used in future trials to harmonize outcome reporting across future studies (21).

**FIGURE 3**




Core outcome set for male infertility research.

*Rimmer. A core outcome set for male infertility research. Fertil Steril 2025.*

Hormonal outcomes, including FSH and testosterone concentration, were discussed during consensus development. Still, a consensus was not reached, so they were not included in the final core outcome set. This is in contrast to the American Urological Association and American Society for Reproductive Medicine guidance on the diagnosis and treatment of Infertility in men (26, 27). This may be due to an imbalance in survey responders between specialists for male infertility compared to general fertility specialists, potentially reflecting a global disparity in education, research, and clinical care focusing on males. While reproductive care in females has been developed and available for over a century, diagnoses and therapies targeted to the male are a relatively recent development. The findings of this study should not be taken to confirm that what was not included in the outcome set ought to be omitted from future studies. Rather, it highlights that more attention must be paid to male reproduction in research, education, and care.

Other outcomes were not included, not due to a lack of importance or them not being required as core outcomes, but due to a lack of reliable and reproducible tools to assess them. Examples include erectile and sexual dysfunction, potentially key outcomes to be considered for interventions in men with erectile dysfunction. However, wider use and ongoing validation of tools such as the Sexual Health Inventory for Men and Erection Hardness Tool may facilitate the inclusion of sexual dysfunction in future studies (28, 29). In addition, there is a paucity of evidence regarding the consistency of patient-reported outcomes in both sexual and erectile dysfunction (30, 31). Another outcome considered but not included was testicular volume. There are differences in practice globally regarding how this is measured and assessed, including orchidometers, beads and callipers, and USS assessments of testicular volume (32). There is also potential inter-observer variation in using both the orchidometer and USS assessment, with three different formulas being used in conjunction with USS assessments to calculate testicular volume (33–35).

## Strengths and limitations

This consensus study is not without limitations. The representativeness of the study's participants should be considered. When considering the Delphi survey, we identified a higher response rate from European participants than from other geographical locations (n = 140/334, 42%). To participate in the Delphi survey, English proficiency, a computer or mobile phone, and internet access were required, which may impact the accessibility of this survey to some potential participants. The overrepresentation of European participants may have influenced which outcomes were prioritized. Ongoing work is needed to build engagement from other geographical regions in future clinical trial design and conduct.

Despite the production of several core outcome sets, including those of the COMMIT initiative, there remains some uncertainty in the methodology for their development

## FIGURE 4

| Outcome | Europe/Africa (n=25) | North/South America (n=11) | Asia/Australia (n=8) | Comments |
|---|---|---|---|---|
| **Sperm concentration - the amount of sperm present in each millilitre of a semen sample** | Combine and report according to WHO manual | Include these 4 outcomes as a minimum but would advise following WHO manual if possible | Combine and report according to WHO manual | Important to include the methodology used when conducting the WHO semen analysis. |
| **Sperm count - the number of sperm that are present in an ejaculate** | | | | |
| **Sperm motility - the proportion of sperm which can move forward or have forward motion and is an indication as to the sperm's ability to travel within the female reproductive tract to fertilise an oocyte** | | | | |
| **Motile sperm count - the number of moving sperm in an ejaculate** | | | | |
| **Spontaneous pregnancy - a woman becoming pregnant without any medical intervention** | Include | Include - use ART conceived / non-ART conceived | Exclude | Exclude as this didn't reach consensus. |
| **Intrauterine pregnancy confirmed by ultrasound - ultrasound scan showing a pregnancy within the uterus** | Included already | | | |
| **Singleton pregnancy - when one baby growing inside the womb** | Included already | | | |
| **Early pregnancy loss - a miscarriage occurring during the first 12 weeks of pregnancy** | Included already | | | |
| **Neonatal mortality - babies that die in the first 28 days of life** | Included already | | | |
| **Chromosomal anomalies - where is an error in the genetic make up, usually leading to a birth defect or disorder** | Exclude | Exclude | Exclude | Challenging and expensive to implement. |
| **Structural malformations - a baby that is born with an abnormality in part of its body such as the heart or spine** | Included already | | | |
| **Ejaculatory dysfunction - unable to ejaculate during intercourse or masturbation** | Exclude | Exclude | Exclude | No good definition or assessment tool. |
| **Testicular atrophy - shrinkage of the testicle** | Exclude | Exclude | Exclude | No good definition or assessment tool for this or testicular volume. |
| **FSH (Male)** | Exclude | Include | Exclude | FSH / testosterone may be of use in certain studies but are not essential. |
| **Testosterone** | Exclude | Include | Exclude | |

WHO – The WHO manual, the 6th edition of the WHO laboratory manual for examining and processing human semen (World Health Organization, 2021).

Green – outcomes where a consensus was reached and should be included in the core outcome set.

Yellow – outcomes where a consensus was not reached.

Red – outcomes where a consensus was reached and should not be included in the core outcome set.

**Summary of consensus meeting discussions.** WHO—The WHO manual, the 6th edition of the WHO laboratory manual for examining and processing human semen (21). Green—outcomes where a consensus was reached and should be included in the core outcome set. Yellow—outcomes where a consensus was not reached. Red—outcomes where a consensus was reached and should not be included in the core outcome set.

*Rimmer. A core outcome set for male infertility research. Fertil Steril 2025.*

(17, 36, 37). The optimal approach to selecting participants, structuring interactions, and methods of synthesizing individual judgments are unclear (19). To address this issue, based on the success of past core outcome set development, we followed the same methodology employed to develop this outcome set. Further research is required to inform future core outcome set development (17).

The attrition rate of Delphi was 36%, which is comparable to other core outcome development studies (38, 39). It may have been possible to reduce attrition by reducing the survey length; for example, limiting the outcomes entered into the Delphi survey, removing outcomes which reached consensus in subsequent survey rounds, or reducing the number of survey rounds. However, attrition needed to be balanced with the requirement to enter a comprehensive list of potential core outcomes into the Delphi survey and for participants to be able to reflect on and rescore individual outcomes in relation to each other.

Many international initiatives, professional societies, and colleagues have advocated for collecting and reporting core outcomes, including live birth, pregnancy loss, and adverse events (40–43). Despite the clear articulation of their importance, poor reporting persists, with only one-third of infertility trials reporting live births (44). The term male infertility has been defined by numerous specialist societies and resulted in similar but distinct definitions being used (26, 27, 45, 46). It is not anticipated that these differences in how male infertility is defined will impact recruitment to future studies.

## Implementing a core outcome set for male infertility research

The COMMIT initiative has developed a strategic plan, in consultation with a broad range of stakeholders across the research pipeline, to utilize available enablers to secure the routine selection, collection, and reporting of core outcomes in future fertility research (47). In addition to researchers, funding bodies are increasingly advocating for the use of core outcome sets within the research they fund. It is considered good practice for researchers planning RCTs to follow the Standard Protocol Item: Recommendations for Interventional Trials (SPIRIT) statement, which outlines the scientific, ethical, and administrative elements that should be incorporated into clinical trial protocols (48). The SPIRIT statement specifically recommends the collection and reporting of core outcomes.

The Core Outcomes in Women's Health (CROWN) Initiative was supported by over 80 specialty journals, including the Cochrane Gynaecology and Fertility Group, *Fertility and Sterility* and *Human Reproduction*, which have resolved to implement this core outcome set (The Core Outcomes in Women's Health Initiative, 2014). CROWN initiative journals will advise researchers to report the core outcome set for infertility within trial reports and offer conclusions based on these outcomes. Where core outcome sets have not been collected, the researchers will be asked to report this deficiency and its implications for their findings. The Cochrane Gynaecology and Fertility Group has published over 100 systematic reviews evaluating potential treatments for infertility and has committed to implementing the core outcome set for infertility when new and updated reviews are being prepared. Secondary research, including pairwise meta-analyses, individual participant data meta-analyses, and network meta-analyses, will be more influential when infertility and male infertility trials routinely collect and report core outcomes.

The COMMIT initiative has committed to further research to assess the uptake and implementation of the core outcome set for infertility (COMMIT-Implementation). Objectively demonstrating the uptake of the core outcome set for infertility is important to quantify its contribution to improving the value of future research. Assessing the uptake of the core outcome set will be undertaken by examining registry records, published protocols, RCTs, and systematic reviews and undertaking a citation analysis. Further research is planned to examine and understand why researchers do and do not implement the core outcome set for infertility (49). By identifying perceived barriers to implementation, strategies informed by implementation science will be developed to limit and hopefully overcome these barriers.

In summary, this study used formal consensus methods to develop a core outcome set for future RCTs and systematic reviews evaluating potential treatments for male infertility. The core outcome set reported in this study is intended to be used across trials evaluating a broad range of potential fertility treatments with a focus on male infertility.

Using this comprehensive outcome set, and other COMMIT outcome sets, should reduce research waste across future fertility research. Embedding the core outcome set within future male infertility research will help to advance the quality and consistency of research informing clinical practice and enhance the care that people with infertility receive. The development and uptake of this core outcome set can transform male infertility research by improving transparency, reducing heterogeneity, and ultimately guiding clinical decision-making grounded in standardized, patient-relevant outcomes.

## CONCLUSION

This global consensus represents a significant step forward in harmonizing outcome reporting for male infertility trials and systematic reviews, enhancing both research quality and clinical translation for men and their partners worldwide.

## DATA AVAILABILITY

The data underlying this article are available in the article and in its online supplementary material.

## Acknowledgements

Please see Supplementary Table S2—Acknowledgements.

## Funding

This work was funded by The Urology Foundation, Small Project Fund awarded to Michael P Rimmer at the University of Edinburgh, UK. RTM was supported by a United Kingdom

Research and Innovation (UKRI) Future Leaders Fellowship (MR/Y011783/1).

## Conflict of interest

C.L.R.B. is the co-editor in chief of *Human Reproduction* and recipient of a BMGF grant and received consultancy fees from Exscentia and Exceed sperm testing, paid to the University of Dundee and speaking fees or honoraria paid personally by Ferring, Copper Surgical and RBMO. R.P.B. receives royalties from Flow diagnósticos. M.L.E. is an advisor to the companies Hannah, Illumicell, Next, Legacy, Doveras, Vseat and received a consultancy fee for this. B.W.M. is a paid consultant for Norgine and Organon and has received research funding from Ferring and Merck, he also receives consultancy and travel support from Merck. R.R.H. received royalties from Elsevier for a book, consultancy fees from Glyciome, and presentation fees from GryNumber Health and Aytu Bioscience. Attendance at Fertility 2020 and Roadshow South Africa by Ralf Henkel was funded by LogixX Pharma Ltd. R.R.H. is also Editor in Chief of *Andrologia* and has been an employee of LogixX Pharma Ltd. since 2020. M.S.K. has been an associate editor with *Human Reproduction Open*. K.Mc.E. received funding to attend Fertility 2025 by the British Fertility Society and is the Chair of the British Fertility Society. He is a member of the HFEA's Scientific and Clinical Advances Advisory Committee and a Committee Member of the NICE Fertility Problems Guideline Group. M.H.V.L. receives consultation fees for the WHO Manual Spanish translation, and travel expenses for the ESHRE MRHI meeting in Budapest. She is a member of the editorial board for *Fertility & Sterility*, *F&S Science*, *Human Reproduction*, and *Frontiers in Endocrinology*. She is also a panel member of the World Health Organization (WHO) Human Reproduction Programme (HRP) Research Project Review Panel. R.S.M. is a member of the NICE Guideline Committee on Fertility and former chair of the British Fertility Society. A. Perheentupa receives an honoraria for lecturing from Merck for the Tackling Infertility manifest, Gedeon Richter & Ferring. A. Perheentupa declares lecture honoraria from Merck, Gideon Richter, and Ferring; and payment from Merck for the Tackling Infertility manifesto. A. Pacey receives consultancy fees for Carrot Fertility and Cryos International as well as lecturing for IBSA Institut Biochimique SA and Mealis Group—all fees paid to The University of Manchester. He is also a Trustee of Progress Educational. Trust (Charity Number 1139856) and Chairman of UKNEQAS Reproductive Sciences Advisory Committee. F.T. is the recipient of a Bayer research grant, as well as DFG Clinical Research Unit 'Male Germ Cells' (CRU326, project number 329621271) and BMBF Junior Scientist Research Centre 'ReproTrack.MS' (grant 01GR2303), he has received travel support from IBSA and Organon. M.v.W. is the Editor-in-Chief of *Human Reproduction Update*. R.W. is a former Deputy Editor of *Human Reproduction* and is currently a Deputy Editor of *Human Reproduction Update*.

## SUPPLEMENTAL MATERIAL

Supplemental data for this article can be found online at https://doi.org/10.1016/j.fertnstert.2025.03.009.

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**Conjunto de criterios de valoración básicos para la futura investigación de la infertilidad masculina: desarrollo de un consenso internacional**

**Objetivo:** desarrollar un conjunto de criterios de valoración básicos para los ensayos de infertilidad masculina.

**Diseño:** se llevó a cabo una encuesta Delphi de dos rondas y un taller de desarrollo de consenso con profesionales de la salud, investigadores y clínicos de todo el mundo.

**Sujetos:** 334 participantes de 39 países participaron en la encuesta Delphi, mientras que 44 participantes de 21 países participaron en el taller de desarrollo de consenso.

**Exposición:** no aplica.

**Criterios de valoración principales:** el conjunto de criterios de valoración principales para los ensayos de infertilidad masculina se desarrolló mediante la inclusión de criterios específicos del factor masculino, además del conjunto de criterios principales de infertilidad general que se centra en los criterios de valoración del factor femenino.

**Resultados:** los criterios de valoración identificados incluyen la evaluación del semen utilizando las recomendaciones de la Organización Mundial de la Salud para el análisis de semen; el embarazo intrauterino viable confirmado por ecografía (teniendo en cuenta los embarazos únicos, gemelares y múltiples superiores); la pérdida del embarazo (teniendo en cuenta el embarazo ectópico, el aborto espontáneo, el mortinato y la interrupción del embarazo); el nacido vivo; la edad gestacional en el momento del parto; el peso al nacer; la mortalidad neonatal; y las anomalías congénitas mayores. Se identificaron otros criterios de valoración potencialmente útiles en determinados contextos de estudio, aunque estos no son un requisito como parte del conjunto de criterios de valoración básicos.

**Conclusiones:** la incorporación del conjunto de criterios de valoración básicos en los ensayos controlados aleatorizados y las revisiones sistemáticas debería garantizar la selección, recopilación y notificación exhaustivas de dichos criterios, que en la actualidad se notifican de forma incoherente. Los organismos de financiación de investigaciones, la declaración Elementos del protocolo estándar: Recomendaciones para ensayos intervencionistas (SPIRIT) y más de 80 revistas especializadas, incluyendo el Grupo Cochrane de Ginecología y Fertilidad, *Fertility and Sterility* y *Human Reproduction*, se han comprometido a implementar este conjunto de criterios de valoración básicos para los ensayos de infertilidad masculina.